P&T Committee Meeting Minutes
Commercial, Exchange, & CHIP
December 2022 e-vote

Class Reviews

ANTI-INFLAMATORY BIOLOGIC REVIEW

Psoriasis:

PSORIASIS			
Brand Name	**Generic**	**Generic Available?**	**Manufacturer**
Tumor Necrosis Factor (TNF) Inhibitors			
Humira	adalimumab	No	AbbVie
Enbrel	etanercept	No	Amgen
Cimzia	certolizumab Pegol	No	UCB
Interleukin-12/Interleukin-23 Antagonists			
Stelara	ustekinumab	No	Johnson & Johnson
Interleukin-23 Antagonist			
Tremfya	guselkumab	No	Johnson & Johnson
Ilumya	tildrakizumab	No	Sun
Skyrizi	risankizumab	No	AbbVie
Interleukin-17 Antagonist			
Cosentyx	secukinumab	No	Novartis
Taltz	ixekizumab	No	Lilly
Siliq	brodalumab	No	AstraZeneca
Phosphodiesterase-4 Enzyme Inhibitor			
Otezla	apremilast	No	Amgen

Recommendation:

Commercial (Traditional) /Exchange (Marketplace) /CHIP (Kids)		
Medication	**Current Policy**	**Recommendations**
Humira (adalimumab)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 84.0** • Medical record documentation that Humira is prescribed by a dermatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND**	No changes recommended at this time.

	• Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND** • Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical corticosteroids **AND** at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine) or phototherapy **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND** • Medical record documentation that Humira is being dosed at a maximum of 40 mg every other week **OR** medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling **AND** • Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	
Enbrel (etanercept)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 41.0** • Medical record documentation that Enbrel is prescribed by a dermatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND** • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cosentyx* AND Humira* **AND** • Medical record documentation that Enbrel is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	**Update:** • Medical record documentation that Enbrel is prescribed by a dermatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND** • ~~Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cosentyx* AND Humira* AND~~ • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topical corticosteroids **AND** at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine) or phototherapy **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND** • Medical record documentation that Enbrel is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

Otezla (apremilast)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 336.0** • Medical record documentation that Otezla is prescribed by a dermatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • For mild disease: ○ Medical record documentation of a diagnosis of mild to moderate plaque psoriasis characterized by less than 5% of body surface area involved **AND** ○ Medical record documentation of an intolerance to, contraindication to, or therapeutic failure of 2 topical therapies (one of which is a corticosteroid of at least medium potency) **AND** ○ Medical record documentation of an intolerance to, contraindication to, or therapeutic failure of phototherapy • For moderate-severe disease: ○ Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND** ○ Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Cosentyx* **AND** Humira*	**Update:** • Medical record documentation that Otezla is prescribed by a dermatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • For mild disease: ○ Medical record documentation of a diagnosis of mild to moderate plaque psoriasis characterized by less than 5% of body surface area involved **AND** ○ Medical record documentation of an intolerance to, contraindication to, or therapeutic failure of 2 topical therapies (one of which is a corticosteroid of at least medium potency) **AND** ○ Medical record documentation of an intolerance to, contraindication to, or therapeutic failure of phototherapy • For moderate-severe disease: ○ Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND** ~~○ Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Cosentyx* **AND** Humira*~~ ○ Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical corticosteroids **AND** at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine) or phototherapy **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy
Skyrizi (risankizumab)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** NF, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 580.0** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation that Skyrizi is prescribed by a dermatologist **AND**	**Update:** **Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation that Skyrizi is prescribed by a dermatologist **AND**

	• Medical record documentation of a diagnosis of moderate to severe plaque psoriasis with greater than or equal to 5% body surface area involved **OR** disease involving crucial areas of the body such as hands, feet, face, and/or genitals **AND** • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cosentyx* **AND** Humira* **AND** • Medical record documentation that Skyrizi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	• Medical record documentation of a diagnosis of moderate to severe plaque psoriasis with greater than or equal to 5% body surface area involved **OR** disease involving crucial areas of the body such as hands, feet, face, and/or genitals **AND** • ~~Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cosentyx* **AND** Humira* **AND**~~ • Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical corticosteroids **AND** at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine) or phototherapy **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND** • Medical record documentation that Skyrizi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent
Tremfya (guselkumab)	**Commercial:** NF, PA-NSO, QL, SP **Exchange:** NF, QL, SP **CHIP:** NF, PA-NSO, QL, SP **Current Pharmacy Policy 484.0** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation that Tremfya is prescribed by a dermatologist **AND** • Medical record documentation of a diagnosis of moderate to severe plaque psoriasis with greater than or equal to 5% body surface area involved **OR** disease involving crucial areas of the body such as hands, feet, face, and/or genitals **AND** • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Cosentyx* **AND** Humira* **AND** • Medical record documentation that Tremfya is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	**Update:** **Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation that Tremfya is prescribed by a dermatologist **AND** • Medical record documentation of a diagnosis of moderate to severe plaque psoriasis with greater than or equal to 5% body surface area involved **OR** disease involving crucial areas of the body such as hands, feet, face, and/or genitals **AND** • ~~Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Cosentyx* **AND** Humira* **AND**~~ • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topical corticosteroids **AND** at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine) or phototherapy **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**

		• Medical record documentation that Tremfya is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent
Cosentyx (secukinumab)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 379.0** • Medical record documentation that Cosentyx is prescribed by a dermatologist **AND** • Medical record documentation of age greater than or equal to 6 years **AND** • Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5 % of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND** • Medical record documentation that Cosentyx is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND** • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topical corticosteroids **AND** at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine or phototherapy **OR** medical record documentation of therapeutic failure on or intolerance to prior biologic therapy	No changes recommended at this time.
Ilumya (tildrakizumab	**Commercial:** Brand NP, PA-NSO, QL, SP (NF effective 1/1/23 approved at 9/22 P&T) **Exchange:** Specialty, PA-NSO, QL, SP (NF effective 1/1/23 approved at /22 P&T) **CHIP:** Brand, PA-NSO, QL, SP (NF effective 1/1/23 approved at 9/22 P&T) **Current Medical Policy MBP 190.0** • Prescribed by a dermatologist **AND** • Medical record documentation that the patient is 18 years of age or older **AND** • Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% body surface area involved or disease affecting crucial body areas such as the hands, feet, face, or genitals **AND** • Medical record documentation that Ilumya is not being used concurrently with a TNF blocker or other biologic agent **AND**	**Update:** • Prescribed by a dermatologist **AND** • Medical record documentation that the patient is 18 years of age or older **AND** • Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% body surface area involved or disease affecting crucial body areas such as the hands, feet, face, or genitals **AND** • Medical record documentation that Ilumya is not being used concurrently with a TNF blocker or other biologic agent **AND** • Medical record documentation of an inadequate response to, contraindication to, or failure on at least 3 months of ~~Humira AND Cosentyx~~ of two (2) preferred formulary biologics for the treatment of psoriasis Formulary Alternatives:

	• Medical record documentation of an inadequate response to, contraindication to, or failure on at least 3 months of Humira **AND** Cosentyx	Enbrel, Humira, Otezla, Skyrizi, Tremfya, Cosentyx
Siliq (brodalumab)	**Commercial:** NF, QL, SP **Exchange:** NF, QL, SP **CHIP:** NF, QL, SP **Current Pharmacy Policy 468.0** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation that Siliq is prescribed by a dermatologist **AND** • Medical record documentation of a diagnosis of moderate-to-severe plaque psoriasis with greater than or equal to 5% body surface area involved **OR** disease involving crucial areas of the body such as hands, feet, face, and/or genitals **AND** • Medical record documentation that member does not have a history of suicidal thoughts or ideations **AND** • Medical record documentation that member does not have a history of depression **OR** medical record documentation of a concomitant diagnosis of depression and documentation that a psychiatric evaluation has been completed and member has been deemed an appropriate candidate for therapy **AND** • Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Cosentyx* **AND** Humira* **AND** • Medical record documentation that Siliq is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	**Update:** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation that Siliq is prescribed by a dermatologist **AND** • Medical record documentation of a diagnosis of moderate-to-severe plaque psoriasis with greater than or equal to 5% body surface area involved **OR** disease involving crucial areas of the body such as hands, feet, face, and/or genitals **AND** • Medical record documentation that member does not have a history of suicidal thoughts or ideations **AND** • Medical record documentation that member does not have a history of depression **OR** medical record documentation of a concomitant diagnosis of depression and documentation that a psychiatric evaluation has been completed and member has been deemed an appropriate candidate for therapy **AND** • Medical record documentation of an inadequate response to, contraindication to, or failure on at least 3 months of ~~Humira AND Cosentyx~~ of two (2) preferred formulary biologics for the treatment of psoriasis • Medical record documentation that Siliq is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent Formulary Alternatives: Enbrel, Humira, Otezla, Skyrizi, Tremfya, Cosentyx
Cimzia (certolizumab pegol)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 197.0** • Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND** • Medical record documentation that Cimzia is prescribed by a dermatologist **AND**	**Update:** • Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND** • Medical record documentation that Cimzia is prescribed by a dermatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND**

	• Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Cosentyx* **AND** Humira* **AND** • Medical record documentation that Cimzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	• Medical record documentation of an inadequate response to, contraindication to, or failure on at least 3 months of ~~Humira AND Cosentyx~~ of two (2) preferred formulary biologics for the treatment of psoriasis • Medical record documentation that Cimzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent Formulary Alternatives: Enbrel, Humira, Otezla, Skyrizi, Tremfya, Cosentyx
Stelara (ustekinumab)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Currently Pharmacy Policy 318.0 & MBP 75.0** • Medical record documentation that Stelara is prescribed by a dermatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease affecting crucial body areas such as hands, feet, face or genitals **AND** • Medical record documentation of an intolerance to, contraindication to or therapeutic failure on a minimum 3 month trial of Cosentyx* **AND** Humira* **AND** • Medical record documentation that the prescribed dosing is appropriate for patient's weight **AND** • Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	**Update:** • Medical record documentation that Stelara is prescribed by a dermatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease affecting crucial body areas such as hands, feet, face or genitals **AND** • Medical record documentation of an intolerance to, contraindication to or therapeutic failure on ~~a minimum 3 month trial of Cosentyx* AND Humira* AND~~ four (4) preferred formulary biologics for the treatment of psoriasis • Medical record documentation that the prescribed dosing is appropriate for patient's weight **AND** • Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent Formulary Alternatives: Enbrel, Humira, Otezla, Skyrizi, Tremfya, Cosentyx, Cimzia, Ilumya, Siliq
Taltz (ixekizumab)	**Commercial:** Brand NP, PA-NSO, QL, SP (NF effective 1/1/23 approved at 9/22 P&T) **Exchange:** Specialty, PA-NSO, QL, SP (NF effective 1/1/23 approved at /22 P&T) **CHIP:** Brand, PA-NSO, QL, SP (NF effective 1/1/23 approved at 9/22 P&T) **Currently Pharmacy Policy 431.0**	**Update:** • Medical record documentation that Taltz is prescribed by a dermatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than 5% of body surface area involved or

	• Medical record documentation that Taltz is prescribed by a dermatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND** • Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx* **AND** • Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor TNF blocker or other biologic agent	disease involving crucial body areas such as the hands, feet, face, or genitals **AND** • Medical record documentation of an intolerance to, contraindication to or therapeutic failure on ~~a minimum 3 month trial of Cosentyx* AND Humira* AND~~ four (4) preferred formulary biologics for the treatment of psoriasis • Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor TNF blocker or other biologic agent Formulary Alternatives: Enbrel, Humira, Otezla, Skyrizi, Tremfya, Cosentyx, Cimzia, Ilumya, Siliq

Ulcerative Colitis:

ULCERATIVE COLITIS			
Brand Name	**Generic**	**Generic Available?**	**Manufacturer**
Tumor Necrosis Factor (TNF) Inhibitors			
Humira	adalimumab	No	AbbVie
Simponi	golimumab	No	Janssen Biotech
Interleukin-12/Interleukin-23 Antagonists			
Rinvoq	upadacitinib	No	AbbVie
Xeljanz/XR	tofacitinib	No	Pfizer U.S.
Phosphodiesterase-4 Enzyme Inhibitor			
Zeposia	ozanimod	No	Bristol-Myers Squibb U.S.

Recommendation:

Commercial (Traditional) /Exchange (Marketplace) /CHIP (Kids)		
Medication	**Current Policy**	**Recommendations**
Humira (adalimumab)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 84.0** **Biweekly Dosing** • Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND** • Medical record documentation that Humira is prescribed by a gastroenterologist **AND** • Medical record documentation of age greater than or equal to 5 years **AND**	No changes recommended at this time.

	• Medical record documentation of therapeutic failure on, intolerance to, at least one conventional therapy: corticosteroids, aminosalicylates, or immunomodulators (azathioprine or 6-mercaptopurine (6-MP)) **AND** • Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **Weekly Dosing** • Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND** • Medical record documentation that Humira is prescribed by a gastroenterologist **AND** • Medical record documentation of age greater than or equal to 5 years **AND** • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one conventional therapy: corticosteroids, aminosalicylates, or immunomodulators (e.g. 6-mercaptopurine or azathioprine) **AND** • Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND** • Medical record documentation of one of the following: ○ For an adult: ▪ Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on BIWEEKLY (every other week) administration of Humira **AND** ▪ Medical record documentation that the member has been compliant with BIWEEKLY administration of Humira **AND** ▪ Medical record documentation of inadequate drug trough level (less than 7.5mcg/mL) to support weekly dosing, per American Gastroenterological Association (AGA) guidelines **OR** ▪ Medical record documentation that weekly dosing was initiated prior to the member turning 18 years and the member is well-controlled on this dose ○ For a member less than or equal to 18 years of age: ▪ Medical record documentation that the member is less than 18 years of age and receiving an appropriate dose based on body weight	
Xeljanz (tofacitinib)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP	No changes recommended at this time.

	CHIP: Brand, PA-NSO, QL, SP **Current Pharmacy Policy 273.0** • Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND** • Medical record documentation that Xeljanz or Xeljanz XR is prescribed by a gastroenterologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** • Medical record documentation that Xeljanz is not being used concurrently with a tumor necrosis factor (TNF) blocker, potent immunosuppressant (e.g., azathioprine and cyclosporine), or other biologic agent	
Rinvoq (upadacitinib)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 605.0** • Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND** • Medical record documentation that Rinvoq is prescribed by a gastroenterologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 3 months of therapy with Humira* **AND** • Medical record documentation that Rinvoq is not being used concurrently with a TNF blocker or other biologic agent	No changes recommended at this time.
Simponi (golimumab)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 198.0** • Medical record documentation that Simponi is prescribed by a gastroenterologist **AND** • Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND**	No changes recommended at this time.

	• Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Humira* **AND** • Medical record documentation that Simponi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	
Zeposia (ozanimod)	**Commercial:** Brand Preferred, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 198.0** • Medical record documentation that Zeposia is prescribed by a gastroenterologist **AND** • Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Humira **AND** Entyvio **AND** infliximab **AND** • Medical record documentation that Zeposia is not being used concurrently with a TNF blocker or other biologic agent	**Update:** • Medical record documentation that Zeposia is prescribed by a gastroenterologist **AND** • Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) preferred formulary biologics for the treatment of ulcerative colitis ~~Humira~~ • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Entyvio **AND** infliximab **AND** • Medical record documentation that Zeposia is not being used concurrently with a TNF blocker or other biologic agent Formulary Alternatives: Humira, Rinvoq, Simponi, Xeljanz/XR
Stelara (ustekinumab)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Currently Pharmacy Policy 318.0 & MBP 75.0** • Medical record documentation that Stelara is prescribed by a gastroenterologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of moderately to severely active ulcerative colitis **AND** • Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Entyvio* **AND** infliximab* **AND**	**Update:** • Medical record documentation that Stelara is prescribed by a gastroenterologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of moderately to severely active ulcerative colitis **AND** • Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of three (3) preferred formulary biologics for the treatment of ulcerative colitis ~~Humira*~~ • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Entyvio* **AND** infliximab* **AND**

	• Medical record documentation of Stelara 130 mg vials as IV infusion (for induction therapy) **OR** Stelara 90 mg syringes (for maintenance therapy) being prescribed **AND** • Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	• Medical record documentation of Stelara 130 mg vials as IV infusion (for induction therapy) **OR** Stelara 90 mg syringes (for maintenance therapy) being prescribed **AND** • Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent Formulary Alternatives: Humira, Rinvoq, Simponi, Xeljanz/XR, Zeposia

Ankylosing Spondylitis/Non-Radiographic Axial Spondylarthritis:

ANKYLOSING SPONDYLITIS/NONRADIOGRAPHIC AXIAL SPONDYLOARTHRITIS			
Brand Name	**Generic**	**Generic Available?**	**Manufacturer**
Tumor Necrosis Factor (TNF) Inhibitors			
Humira	adalimumab	No	AbbVie
Enbrel	etanercept	No	Amgen
Cimzia	certolizumab Pegol	No	UCB
Simponi	golimumab	No	Janssen Biotech
Interleukin-12/Interleukin-23 Antagonists			
Rinvoq	upadacitinib	No	AbbVie
Xeljanz/XR	tofacitinib	No	Pfizer U.S.
Interleukin-17 Antagonist			
Cosentyx	secukinumab	No	Novartis
Taltz	ixekizumab	No	Lilly

Recommendation:

Commercial (Traditional) /Exchange (Marketplace) /CHIP (Kids)		
Medication	**Current Policy**	**Recommendations**
Humira (adalimumab) Humira is not FDA approved for nr-axSpA.	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 84.0** • Medical record documentation that Humira is prescribed by a rheumatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of ankylosing spondylitis **AND** • Physician documentation of a therapeutic failure on, contraindication to, or intolerance to an adequate trial of at least	No changes recommended at this time.

	two (2) nonsteroidal anti-inflammatory drugs (NSAIDS) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND** • Medical record documentation that Humira is being dosed at a maximum of 40 mg every other week **OR** medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling **AND** • Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	
Enbrel (etanercept) Enbrel is not FDA approved for nr-axSpA.	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 41.0** • Medical record documentation of a diagnosis of ankylosing spondylitis **AND** • Medical record documentation that Enbrel is prescribed by a rheumatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cosentyx* **AND** Humira* **AND** • Medical record documentation that Enbrel is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	**Update:** • Medical record documentation of a diagnosis of ankylosing spondylitis **AND** • Medical record documentation that Enbrel is prescribed by a rheumatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** ~~• Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cosentyx* AND Humira* AND~~ • Physician documentation of a therapeutic failure on, contraindication to, or intolerance to an adequate trial of at least two (2) nonsteroidal anti-inflammatory drugs (NSAIDS) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND** • Medical record documentation that Enbrel is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent
Cosentyx (secukinumab)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 379.0** <u>Ankylosing Spondylitis</u> • Medical record documentation of a diagnosis of ankylosing spondylitis **AND** • Medical record documentation that Cosentyx is prescribed by a rheumatologist **AND**	No changes recommended at this time.

	• Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of therapeutic failure on or intolerance to prior biologic therapy **AND** • Medical record documentation that Cosentyx is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND** • Medical record documentation that the medication is being dose as 150 mg every 4 weeks with or without a loading dose of 150 mg at Weeks 0, 1, 2, 3, and 4 <u>Non-Radiographic Axial Spondylarthritis</u> • Medical record documentation of a diagnosis of non-radiographic axial spondylarthritis **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation that Cosentyx is prescribed by a rheumatologist **AND** • Medical record documentation of at least one of the following: o C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) **OR** o Sacroiliitis on magnetic resonance imaging (MRI) **AND** • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) nonsteroidal anti-inflammatory drugs (NSAIDs) **AND** • Medical record documentation that Cosentyx is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND** • Medical record documentation that the medication is being dosed as 150 mg every 4 weeks with or without a loading dose of 150 mg at Weeks 0, 1, 2, 3, and 4	
Xeljanz (tofacitinib) Xeljanz is not FDA approved for nr-axSpA.	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 273.0** • Medical record documentation of a diagnosis of ankylosing spondylitis **AND**	**Update:** • Medical record documentation of a diagnosis of ankylosing spondylitis **AND** • Medical record documentation that Xeljanz or Xeljanz XR is prescribed by a rheumatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND**

	• Medical record documentation that Xeljanz or Xeljanz XR is prescribed by a rheumatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx* **AND** • Medical record documentation that Xeljanz or Xeljanz XR is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND** • Medical record documentation that Xeljanz or Xeljanz XR is being dosed consistent with Food and Drug Administration (FDA)-approved labeling	• Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* AND Cosentyx* **OR** Enbrel* **AND** • Medical record documentation that Xeljanz or Xeljanz XR is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND** • Medical record documentation that Xeljanz or Xeljanz XR is being dosed consistent with Food and Drug Administration (FDA)-approved labeling Formulary Alternatives: Humira, Enbrel
Rinvoq (upadacitinib)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 605.0** • Medical record documentation of a diagnosis of ankylosing spondylitis **AND** • Medical record documentation that Rinvoq is prescribed by a rheumatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx* **AND** • Medical record documentation that Rinvoq is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	**Update:** <u>Ankylosing Spondylitis</u> • Medical record documentation of a diagnosis of ankylosing spondylitis **AND** • Medical record documentation that Rinvoq is prescribed by a rheumatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* AND Cosentyx* **OR** Enbrel* **AND** • Medical record documentation that Rinvoq is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent Non-Radiographic Axial Spondylarthritis is a new indication presented in separate fast fact. Formulary Alternatives: Humira, Enbrel
Cimzia (certolizumab pegol)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 197.0** <u>Ankylosing Spondylitis</u> • Medical record documentation of a diagnosis of ankylosing spondylitis **AND**	**Update:** <u>Ankylosing Spondylitis</u> • Medical record documentation of a diagnosis of ankylosing spondylitis **AND** • Medical record documentation that Cimzia is prescribed by a rheumatologist **AND**

	• Medical record documentation that Cimzia is prescribed by a rheumatologist **AND**
	• Medical record documentation of age greater than or equal to 18 years **AND**
	• Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Cosentyx* **AND** Humira* **AND**
	• Medical record documentation that Cimzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent
	
	<u>Non-Radiographic Axial Spondylarthritis</u>
	• Medical record documentation of a diagnosis of non-radiographic axial spondylarthritis **AND**
	• Medical record documentation of age greater than or equal to 18 years **AND**
	• Medical record documentation that Cimzia is prescribed by a rheumatologist **AND**
	• Medical record documentation of at least one of the following:
	  ○ C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) **OR**
	  ○ Sacroiliitis on magnetic resonance imaging (MRI)
	AND
	• Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) nonsteroidal anti-inflammatory drugs (NSAIDs) **AND**
	• Medical record documentation that Cimzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent
		• Medical record documentation of age greater than or equal to 18 years **AND**
		• Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of ~~Cosentyx* AND Humira*~~ of two (2) preferred formulary biologics for the treatment of ankylosing spondylitis **AND**
		• Medical record documentation that Cimzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent
		
		Formulary Alternatives:
		Enbrel, Humira, Cosentyx, Rinvoq, Xeljanz XR
		
		<u>Non-Radiographic Axial Spondylarthritis</u>
		No changes recommended at this time.

Simponi (golimumab) Simponi is not FDA approved for nr-axSpA.	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 198.0** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation that Simponi is prescribed by a rheumatologist **AND** • Medical record documentation of a diagnosis of ankylosing spondylitis **AND**	**Update:** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation that Simponi is prescribed by a rheumatologist **AND** • Medical record documentation of a diagnosis of ankylosing spondylitis **AND** • Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of ~~Cosentyx* AND Humira*~~ of two (2) preferred formulary biologics for the treatment of ankylosing spondylitis **AND**

	• Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Cosentyx* **AND** Humira* **AND** • Medical record documentation that Simponi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	• Medical record documentation that Simponi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent Formulary Alternatives: Enbrel, Humira, Cosentyx, Rinvoq, Xeljanz XR
Taltz (ixekizumab)	**Commercial:** Brand NP, PA-NSO, QL, SP (NF effective 1/1/23 approved at 9/22 P&T) **Exchange:** Specialty, PA-NSO, QL, SP (NF effective 1/1/23 approved at /22 P&T) **CHIP:** Brand, PA-NSO, QL, SP (NF effective 1/1/23 approved at 9/22 P&T) **Currently Pharmacy Policy 431.0** <u>Ankylosing Spondylitis</u> • Medical record documentation that Taltz is prescribed by a rheumatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of ankylosing spondylitis **AND** • Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx* **AND** • Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent <u>Non-Radiographic Axial Spondylarthritis</u> • Medical record documentation that Taltz is prescribed by a rheumatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of non-radiographic axial spondylarthritis **AND** • Medical record documentation of at least one of the following: ○ C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) **OR** ○ Sacroiliitis on magnetic resonance imaging (MRI) **AND**	**Update:** <u>Ankylosing Spondylitis</u> • Medical record documentation that Taltz is prescribed by a rheumatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of ankylosing spondylitis **AND** • Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of ~~Humira* AND Cosentyx*~~ of three (3) preferred formulary biologics for the treatment of ankylosing spondylitis **AND** • Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent Formulary Alternatives: Enbrel, Humira, Cosentyx, Rinvoq, Xeljanz XR <u>Non-Radiographic Axial Spondylarthritis</u> • Medical record documentation that Taltz is prescribed by a rheumatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of non-radiographic axial spondylarthritis **AND** • Medical record documentation of at least one of the following: ○ C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) **OR** ○ Sacroiliitis on magnetic resonance imaging (MRI) **AND** • Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of ~~Cosentyx*~~ of three (3) preferred

	• Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Cosentyx* **AND** • Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	formulary biologics for the treatment of non-radiogaphic axial spondylarthritis **AND** • Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent Formulary Alternatives: Cosentyx, Cimzia, Rinvoq

Juvenile Idiopathic Arthritis:

JUVENILE IDIOPATHIC ARTHRITIS			
Brand Name	**Generic**	**Generic Available?**	**Manufacturer**
Tumor Necrosis Factor (TNF) Inhibitors			
Humira	adalimumab	No	AbbVie
Enbrel	etanercept	No	Amgen
Interleukin-12/Interleukin-23 Antagonists			
Xeljanz/XR	tofacitinib	No	Pfizer U.S.
Selective T-Cell Co-stimulation Blocker			
Orencia	abatacept	No	Bristol-Myers Squibb
Interleukin-6 (IL-6) Receptor Antagonists			
Actemra	Tocilizumab	No	Roche

Recommendation:

Commercial (Traditional) /Exchange (Marketplace) /CHIP (Kids)		
Medication	**Current Policy**	**Recommendations**
Humira (adalimumab)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 84.0** • Medical record documentation of age greater than or equal to 2 years **AND** • Medical record documentation that Humira is prescribed by a rheumatologist **AND** • Medical record documentation of a diagnosis of active polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND** • Medical record documentation of an inadequate response to a minimum 3 month trial of both nonsteroidal anti-inflammatory drug (NSAID) therapy **AND** methotrexate or other disease modifying anti-rheumatic drug (DMARD) if methotrexate therapy is contraindicated **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**	No changes recommended at this time.

	• Medical record documentation that Humira is being dosed at a maximum of 40 mg every other week **OR** medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling **AND** • Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	
Enbrel (etanercept)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 41.0** • Medical record documentation of age greater than or equal to 2 years **AND** • Medical record documentation that Enbrel is prescribed by a rheumatologist **AND** • Medical record documentation of a diagnosis of moderate to severely active polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND** • Medical record documentation of an inadequate response to a minimum 3 month trial of both NSAID therapy **AND** methotrexate or other DMARD if methotrexate therapy is contraindicated **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND** • Medical record documentation that Enbrel is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	No changes recommended at this time.
Xeljanz (tofacitinib)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 273.0** • Medical record documentation of a diagnosis of active polyarticular course juvenile idiopathic arthritis **AND** • Medical record documentation of age greater than or equal to 2 years **AND** • Medical record documentation that Xeljanz is prescribed by a rheumatologist **AND**	**Update:** • Medical record documentation of a diagnosis of active polyarticular course juvenile idiopathic arthritis **AND** • Medical record documentation of age greater than or equal to 2 years **AND** • Medical record documentation that Xeljanz is prescribed by a rheumatologist **AND** • Medical record documentation of an inadequate response to a minimum 3 month trial of Humira* **OR** Enbrel* **AND**

	• Medical record documentation of an inadequate response to a minimum 3 month trial of Humira* **AND** • Medical record documentation that Xeljanz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND** • Medical record documentation that Xeljanz or Xeljanz oral solution is being dosed consistent with Food and Drug Administration (FDA)-approved labeling	• Medical record documentation that Xeljanz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND** • Medical record documentation that Xeljanz or Xeljanz oral solution is being dosed consistent with Food and Drug Administration (FDA)-approved labeling Formulary Alternatives: Humira, Enbrel
Orencia (abatacept)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 253.0** • Medical record documentation of age greater than or equal to 2 years **AND** • Medical record documentation of a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND** • Medical record documentation that subcutaneous Orencia is prescribed by a rheumatologist **AND** • Medical record documentation of an inadequate response to a minimum 4 month trial of one preferred tumor necrosis factor (TNF)-alpha inhibitor (Humira* **OR** Enbrel*) **AND** • If Orencia ClickJect autoinjector is prescribed: Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation that Orencia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	**Update:** • Medical record documentation of age greater than or equal to 2 years **AND** • Medical record documentation of a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND** • Medical record documentation that subcutaneous Orencia is prescribed by a rheumatologist **AND** • Medical record documentation of an inadequate response to a minimum ~~4 month trial of one preferred tumor necrosis factor (TNF)-alpha inhibitor (Humira* **OR** Enbrel*)~~ 3 month trial of two (2) preferred formulary biologics for the treatment of juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND** • If Orencia ClickJect autoinjector is prescribed: Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation that Orencia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent Formulary Alternatives: Humira, Enbrel, Xeljanz
Actemra (tocilizumab)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 321.0** • Medical record documentation that Actemra Self Injectable is prescribed by a rheumatologist **AND** • Medical record documentation of a diagnosis of active polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND** • Medical record documentation of age greater than or equal to 2 years **AND**	**Update:** • Medical record documentation that Actemra Self Injectable is prescribed by a rheumatologist **AND** • Medical record documentation of a diagnosis of active polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND** • Medical record documentation of age greater than or equal to 2 years **AND** • Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum

	• Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** • Medical record documentation that Actemra is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	3 month trial of ~~Humira*~~ two (2) preferred formulary biologics for the treatment of juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND** • Medical record documentation that Actemra is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent Formulary Alternatives: Humira, Enbrel, Xeljanz

Psoriatic Arthritis:

PSORIATIC ARTHRITIS			
Brand Name	**Generic**	**Generic Available?**	**Manufacturer**
Tumor Necrosis Factor (TNF) Inhibitors			
Humira	adalimumab	No	AbbVie
Enbrel	etanercept	No	Amgen
Cimzia	certolizumab Pegol	No	UCB
Simponi	golimumab	No	Janssen Biotech
Interleukin-12/Interleukin-23 Antagonists			
Stelara	ustekinumab	No	Johnson & Johnson
Interleukin-23 Antagonist			
Tremfya	guselkumab	No	Johnson & Johnson
Skyrizi	risankizumab	No	AbbVie
Interleukin-17 Antagonist			
Cosentyx	secukinumab	No	Novartis
Taltz	ixekizumab	No	Lilly
Phosphodiesterase-4 Enzyme Inhibitor			
Otezla	apremilast	No	Amgen
Interleukin-12/Interleukin-23 Antagonists			
Rinvoq	upadacitinib	No	AbbVie
Xeljanz/XR	tofacitinib	No	Pfizer U.S.
Selective T-Cell Co-stimulation Blocker			
Orencia	abatacept	No	Bristol-Myers Squibb

Recommendation:

Commercial (Traditional) /Exchange (Marketplace) /CHIP (Kids)		
Medication	**Current Policy**	**Recommendations**
Humira (adalimumab)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP	**Update:** • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include ~~the following:~~ documentation of either

	Current Pharmacy Policy 84.0 • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following: ○ Documentation of either active psoriatic lesions or a documented history of psoriasis **AND** • Medical record documentation that Humira is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • <u>For peripheral disease</u>: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate **AND** an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR** • <u>For axial disease</u>: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND** • Medical record documentation that Humira is being dosed at a maximum of 40 mg every other week **OR** medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling **AND** • Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	active psoriatic lesions or a documented history of psoriasis **AND** • Medical record documentation that Humira is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • <u>For peripheral disease</u>: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate **AND** an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR** • <u>For axial disease</u>: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND** • Medical record documentation that Humira is being dosed at a maximum of 40 mg every other week **OR** medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling **AND** • Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent
Enbrel (etanercept)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 41.0** • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following: • Documentation of either active psoriatic lesions or a documented history of psoriasis **AND** • Medical record documentation that Enbrel is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cosentyx* **AND** Humira* **AND**	**Update:** • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include ~~the following:~~ documentation of either active psoriatic lesions or a documented history of psoriasis **AND** • Medical record documentation that Enbrel is prescribed by a rheumatologist or dermatologist **AND** • ~~Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cosentyx* AND Humira* AND~~ • <u>For peripheral disease</u>: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate **AND** an adequate trial of at least

	• Medical record documentation that Enbrel is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR** • For axial disease: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND** • Medical record documentation that Enbrel is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent
Otezla (apremilast)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 336.0** • Medical record documentation that Otezla is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of active psoriatic arthritis which must include the following: ○ Documentation of either active psoriatic lesions or a documented history of psoriasis **AND** • Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least 3 months of therapy with Cosentyx* **AND** Humira*	**Update:** • Medical record documentation that Otezla is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include ~~the following:~~ documentation of either active psoriatic lesions or a documented history of psoriasis **AND** ~~• Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least 3 months of therapy with Cosentyx* **AND** Humira*~~ • For peripheral disease: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate **AND** an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR** • For axial disease: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy
Skyrizi (risankizumab)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** NF, QL, SP **CHIP:** Brand, PA-NSO, QL, SP	**Update:** **Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP

	Current Pharmacy Policy 580.0 • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation that Skyrizi is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation of active psoriatic arthritis which must include the following: ○ Documentation of either active psoriatic lesions or a documented history of psoriasis **AND** • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cosentyx* **AND** Humira* **AND** • Medical record documentation that Skyrizi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	• Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation that Skyrizi is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include ~~the following:~~ documentation of either active psoriatic lesions or a documented history of psoriasis **AND** • ~~Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cosentyx* AND Humira* AND~~ • For peripheral disease: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate **AND** an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR** • For axial disease: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND** • Medical record documentation that Skyrizi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent
Tremfya (guselkumab)	**Commercial:** NF, PA-NSO, QL, SP **Exchange:** NF, QL, SP **CHIP:** NF, PA-NSO, QL, SP **Current Pharmacy Policy 484.0** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation that Tremfya is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation of active psoriatic arthritis which must include documentation of either active psoriatic lesions or a documented history of psoriasis **AND**	**Update:** **Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation that Tremfya is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation of active psoriatic arthritis which must include documentation of either active psoriatic lesions or a documented history of psoriasis **AND**

	• Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Cosentyx* **AND** Humira*	• ~~Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Cosentyx* AND Humira*~~ • For peripheral disease: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate **AND** an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR** • For axial disease: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND** • Medical record documentation that Tremfya is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent
Cosentyx (secukinumab)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 379.0** • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following: ○ Documentation of either active psoriatic lesions or a documentation history of psoriasis **AND** • Medical record documentation that Cosentyx is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation of age greater than or equal to 2 years **AND** • Medical record documentation that Cosentyx is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND** • **For peripheral disease**: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to methotrexate **AND** an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of therapeutic failure on or intolerance to prior biologic therapy **OR** • **For axial disease**: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to an adequate trial of	**Update:** • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include ~~the following:~~ documentation of either active psoriatic lesions or a documented history of psoriasis **AND** • Medical record documentation that Cosentyx is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation of age greater than or equal to 2 years **AND** • Medical record documentation that Cosentyx is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND** • **For peripheral disease**: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to methotrexate **AND** an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of therapeutic failure on or intolerance to prior biologic therapy **OR** • **For axial disease**: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR**

	at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of therapeutic failure on or intolerance to prior biologic therapy **AND** • If the request is for a pediatric member, medical record documentation that the prescribed dosing is appropriate for member's weight	medical record documentation of therapeutic failure on or intolerance to prior biologic therapy **AND** • If the request is for a pediatric member, medical record documentation that the prescribed dosing is appropriate for member's weight
Xeljanz (tofacitinib)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 273.0** • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following: ○ Documentation of either active psoriatic lesions or a documented history of psoriasis **AND** • Medical record documentation of an inadequate response to or intolerance to a 3-month trial of methotrexate or another disease-modifying antirheumatic drug (DMARD) **AND** • Medical record documentation that Xeljanz or Xeljanz XR is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation that Xeljanz or Xeljanz XR is being prescribed in combination with non-biologic disease modifying antirheumatic drug (DMARD) therapy (including but not limited to methotrexate, sulfasalazine, and/or leflunomide) **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx* **AND** • Medical record documentation that Xeljanz or Xeljanz XR is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND** • Medical record documentation that Xeljanz or Xeljanz XR is being dosed consistent with Food and Drug Administration (FDA)-approved labeling	**Update:** • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include ~~the following:~~ documentation of either active psoriatic lesions or a documented history of psoriasis **AND** • ~~Medical record documentation of an inadequate response to or intolerance to a 3-month trial of methotrexate or another disease-modifying antirheumatic drug (DMARD) **AND**~~ • Medical record documentation that Xeljanz or Xeljanz XR is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation that Xeljanz or Xeljanz XR is being prescribed in combination with non-biologic disease modifying antirheumatic drug (DMARD) therapy (including but not limited to methotrexate, sulfasalazine, and/or leflunomide) **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* ~~**AND** Cosentyx*~~ **OR** Enbrel* **AND** • Medical record documentation that Xeljanz or Xeljanz XR is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND** • Medical record documentation that Xeljanz or Xeljanz XR is being dosed consistent with Food and Drug Administration (FDA)-approved labeling Formulary Alternatives: Humira, Enbrel
Rinvoq (upadacitinib)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP	**Update:** • Medical record documentation of a diagnosis of psoriatic arthritis **AND**

	Current Pharmacy Policy 605.0 • Medical record documentation of a diagnosis of psoriatic arthritis **AND** • Medical record documentation that Rinvoq is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following: ○ Documentation of either active psoriatic lesions or a documented history of psoriasis **AND** • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 3 months of therapy with Cosentyx* **AND** Humira* **AND** • Medical record documentation that Rinvoq is not being used concurrently with a TNF blocker or other biologic agent	• Medical record documentation that Rinvoq is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include ~~the following:~~ documentation of either active psoriatic lesions or a documented history of psoriasis **AND** • Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* ~~AND Cosentyx*~~ **OR** Enbrel* **AND** • Medical record documentation that Rinvoq is not being used concurrently with a TNF blocker or other biologic agent Formulary Alternatives: Humira, Enbrel
Cimzia (certolizumab pegol)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 197.0** • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following: ○ Documentation of either active psoriatic lesions or a documented history of psoriasis **AND** • Medical record documentation that Cimzia is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Cosentyx* **AND** Humira* **AND** • Medical record documentation that Cimzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	**Update:** • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include ~~the following:~~ documentation of either active psoriatic lesions or a documented history of psoriasis **AND** • Medical record documentation that Cimzia is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of an inadequate response to, contraindication to, or failure on at least 3 months ~~Humira AND Cosentyx~~ of two (2) preferred formulary biologics for the treatment of psoriatic arthritis **AND** • Medical record documentation that Cimzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent Formulary Alternatives: Enbrel, Humira, Otezla, Skyrizi, Tremfya, Cosentyx, Rinvoq, Xeljanz/XR
Orencia (abatacept)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP	**Update:**

	CHIP: Brand, PA-NSO, QL, SP **Current Pharmacy Policy 253.0** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following: ○ Documentation of either active psoriatic lesions or a documented history of psoriasis **AND** • Medical record documentation that subcutaneous Orencia is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cosentyx* **AND** Humira* **AND** • Medical record documentation that Orencia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	• Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include ~~the following:~~ documentation of either active psoriatic lesions or a documented history of psoriasis **AND** • Medical record documentation that subcutaneous Orencia is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cosentyx* **AND** Humira* **AND** • Medical record documentation of an inadequate response to, contraindication to, or failure on at least 3 months ~~Cosentyx* AND Humira*~~ of two (2) preferred formulary biologics for the treatment of psoriatic arthritis **AND** • Medical record documentation that Orencia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent Formulary Alternatives: Enbrel, Humira, Otezla, Skyrizi, Tremfya, Cosentyx, Rinvoq, Xeljanz/XR
Simponi (golimumab)	**Commercial:** Brand NP, PA-NSO, QL, SP **Exchange:** Specialty, PA-NSO, QL, SP **CHIP:** Brand, PA-NSO, QL, SP **Current Pharmacy Policy 198.0** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation that Simponi is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation of active psoriatic arthritis which must include the following: • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following: ○ Documentation of either active psoriatic lesions or a documented history of psoriasis **AND** • Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Cosentyx* AND Humira* **AND**	**Update:** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation that Simponi is prescribed by a rheumatologist or dermatologist **AND** • Medical record documentation of active psoriatic arthritis which must include the following: • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include ~~the following:~~ documentation of either active psoriatic lesions or a documented history of psoriasis **AND** • Medical record documentation of an inadequate response to, contraindication to, or failure on at least 3 months ~~Cosentyx* AND Humira*~~ of two (2) preferred formulary biologics for the treatment of psoriatic arthritis **AND**

	• Medical record documentation that Simponi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	• Medical record documentation that Simponi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent Formulary Alternatives: Enbrel, Humira, Otezla, Skyrizi, Tremfya, Cosentyx, Rinvoq, Xeljanz/XR
Stelara (ustekinumab)	New indication presented in separate fast fact.	
Taltz (ixekizumab)	**Commercial:** Brand NP, PA-NSO, QL, SP (NF effective 1/1/23 approved at 9/22 P&T) **Exchange:** Specialty, PA-NSO, QL, SP (NF effective 1/1/23 approved at /22 P&T) **CHIP:** Brand, PA-NSO, QL, SP (NF effective 1/1/23 approved at 9/22 P&T) **Currently Pharmacy Policy 431.0** • Medical record documentation that Taltz is prescribed by a dermatologist or rheumatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following: ○ Documentation of either active psoriatic lesions or a documented history of psoriasis **AND** • Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx* **AND** • Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent	**Update:** • Medical record documentation that Taltz is prescribed by a dermatologist or rheumatologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include ~~the following:~~ documentation of either active psoriatic lesions or a documented history of psoriasis **AND** • Medical record documentation of an inadequate response to, contraindication to, or failure on at least 3 months ~~Cosentyx* AND Humira*~~ of three (3) preferred formulary biologics for the treatment of psoriatic arthritis **AND** • Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent Formulary Alternatives: Enbrel, Humira, Otezla, Skyrizi, Tremfya, Cosentyx, Rinvoq, Xeljanz/XR, Cimzia, Orencia, Simponi

Additional Recommendations:

The following agents were moved to a non-formulary status effective 1/1/2023:

- Kineret
- Olumiant
- Orencia
- Kevzara
- Ilumya
- Taltz

In order to ensure no disruption to our membership, it is recommended that the products currently coded with a PA for new starts only are updated to a standard prior authorization. An initial and ongoing authorization duration of 12 months is recommended with the following re-authorization criteria:

> Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of (insert disease state) on (insert drug name) therapy is required.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

MIGRAINE PREVENTION CLASS REVIEW

Agents for Migraine Prevention			
Brand Name	**Generic**	**Generic Available?**	**Manufacturer**
Calcitonin Gene-Related Peptide Inhibitors			
Aimovig	erenumab-aooe	No	Amgen
Ajovy	fremanezumab-vfrm	No	Teva
Emgality	galcanezumab-gnlm	No	Eli Lilly
Nurtec ODT	rimegepant	No	Biohaven
Qulipta	atogepant	No	Abbvie
Vyepti	eptinezumab-jjmr	No	Lundbeck
Botulinum Toxin			
Botox	onabotulinumtoxinA	No	Allergan

Place in Therapy:

American Headache Society

The gepants for migraine prevention are not currently incorporated into clinical guidelines. However, use of monoclonal antibodies that target CGRP (erenumab, fremanezumab, galcanezumab, eptinezumab) can be considered if:

1. Patient is at least 18 years old and
2. Has migraines with 4-7 monthly headache days and
3. Unable to tolerate/poor response to at least two of the following:
   - Topiramate
   - Divalproex sodium/valproate sodium
   - Metoprolol, propranolol, timolol, atenolol, nadolol
   - Amitriptyline, nortriptyline
   - Venlafaxine, duloxetine

4. Minimum of moderate disability present (MIDAS >11, HIT-6 >50)
1. Patient is at least 18 years old and 2. Has migraines with 8-14 monthly headache days and 3. Unable to tolerate/poor response to at least two of the following: - Topiramate - Divalproex sodium/valproate sodium - Metoprolol, propranolol, timolol, atenolol, nadolol - Amitriptyline, nortriptyline - Venlafaxine, duloxetine
1. Patient is at least 18 years old and 2. Has chronic migraines and 3. Is either unable to tolerate/poor response to at least two of the following: - Topiramate - Divalproex sodium/valproate sodium - Metoprolol, propranolol, timolol, atenolol, nadolol - Amitriptyline, nortriptyline - Venlafaxine, duloxetine 4. Or unable to tolerate/poor response to a minimum of two quarterly injections of onabotulinumtoxinA*

*OnabotulinumtoxinA is indicated only for chronic migraine after failure of at least two oral agents.

Commercial

		No Shift	50% Shift	80% shift
Current Position	Net Cost	$2,995,532		
	Net Cost Change	$0		
	Rebate Yield	$1,232,254		
	Rebate Yield Change	$0		
Option 1 (Nurtec exclusive preferred, injectables 2nd line)	Net Cost		$3,986,544	$4,404,679
	Net Cost Change		$991,012	$1,409,147
	Rebate Yield		$1,337,841	$1,595,010
	Rebate Yield Change		$105,587	$362,756
Option 2 (Qulipta exclusive preferred, injectables 2nd line)	Net Cost		$3,450,798	$3,427,781
	Net Cost Change from Current		$455,266	$432,249
	Rebate Yield		$1,036,869	$964,206
	Rebate Yield Change from Current		-$195,385	-$268,048

Additional UM requirements per rebating:

- There is no restriction requiring a specialist prescriber, referral, or consultation
- Remove requirement of diagnosis (physician attestation is acceptable)

Formatted: Font: (Default) +Headings (Arial), Font color: Text 2

Formatted: Left, Space After: 0 pt, Line spacing: single, Tab stops: Not at 1.08"

Formatted: Font color: Custom Color(RGB(66,66,66))

Formatted: Font color: Custom Color(RGB(66,66,66))

Formatted: Left, Space After: 0 pt, Line spacing: single, Bulleted + Level: 1 + Aligned at: 0.25" + Indent at: 0.5"

Formatted: Font: 11 pt, Not Bold

- Physician attestation is sufficient to determine approval
- The criteria are applied uniformly across the class

Clinical Recommendation:

Medication	Current Policy	Recommendations
Aimovig (erenumab-aooe)	**Aimovig Policy 511.0** - Prescribed by or in consultation with neurologist or headache specialist **AND** - Documentation that patient is 18 years of age or older **AND** - Diagnosis of migraine with or without aura based on ICHD-3 criteria **AND** - Documentation of number of baseline monthly migraine or headache days **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least two of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation that medication will not be used with another CGRP antagonist indicated for preventive treatment of migraine **AND** Documentation that medication will not be concurrently used with botulinum toxin **OR** if being used with botulinum toxin, documentation of therapeutic failure on at least 3-month trial with at least one CGRP antagonist without Botox **AND** documentation of failure of a minimum 6-month trial of Botox without a CGRP antagonist.	**No changes recommended.**
Ajovy (fremanezumab-vfrm)	**Ajovy Policy 532.0** - Prescribed by or in consultation with neurologist or headache specialist **AND** - Documentation that patient is 18 years of age or older **AND** - Diagnosis of migraine with or without aura based on ICHD-3 criteria **AND** - Documentation of number of baseline monthly migraine or headache days **AND**	**Ajovy Policy 532.0** - Prescribed by or in consultation with neurologist or headache specialist **AND** - Documentation that patient is 18 years of age or older **AND** - Diagnosis of migraine with or without aura based on ICHD-3 criteria **AND** - Documentation of number of baseline monthly migraine or headache days **AND**

Formatted: Font color: Custom Color(RGB(66,66,66))
Formatted: Font: 11 pt, Not Bold
Formatted: Font color: Custom Color(RGB(66,66,66))
Formatted: Font color: Custom Color(RGB(66,66,66))
Commented [EMA1]: All-commercial-policies-8-3-22.pdf (geisinger.org)

	- Documentation of therapeutic failure on, intolerance to, or contraindication to at least three of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to Aimovig and Emgality **AND** - Documentation that medication will not be used with another CGRP antagonist indicated for preventive treatment of migraine **AND** - Documentation that medication will not be concurrently used with botulinum toxin **OR** if being used with botulinum toxin, documentation of therapeutic failure on at least 3-month trial with at least one CGRP antagonist without Botox **AND** documentation of failure of a minimum 6-month trial of Botox without a CGRP antagonist	- Documentation of therapeutic failure on, intolerance to, or contraindication to at least ~~three~~ two of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to Aimovig and Emgality **AND** - Documentation that medication will not be used with another CGRP antagonist indicated for preventive treatment of migraine **AND** Documentation that medication will not be concurrently used with botulinum toxin **OR** if being used with botulinum toxin, documentation of therapeutic failure on at least 3-month trial with at least one CGRP antagonist without Botox **AND** documentation of failure of a minimum 6-month trial of Botox without a CGRP antagonist
Emgality (galcanezumab-gnlm)	**Emgality Policy 533.0** - Prescribed by or in consultation with neurologist or headache specialist **AND** - Documentation that patient is 18 years of age or older **AND** - Diagnosis of migraine with or without aura based on ICHD-3 criteria **AND** - Documentation of number of baseline monthly migraine or headache days **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least two of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation that medication will not be used with another CGRP antagonist indicated for preventive treatment of migraine **AND** - Documentation that medication will not be concurrently used with botulinum toxin **OR** if being used with botulinum toxin, documentation of therapeutic failure on at least 3-month trial with at least one CGRP	**No changes recommended.**

	antagonist without Botox **AND** documentation of failure of a minimum 6-month trial of Botox without a CGRP antagonist	
Nurtec ODT (34imegepant)	**Nurtec Policy 629.0** - Prescribed by or in consultation with neurologist or headache specialist **AND** - Documentation that patient is 18 years of age or older **AND** - Diagnosis of migraine with or without aura based on ICHD-3 criteria **AND** - Documentation of number of baseline monthly migraine or headache days **AND** - Documentation of diagnosis of episodic migraine (≤14 headache days per month) **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least three of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to Aimovig and Emgality **AND** - Documentation that medication will not be used with another CGRP antagonist indicated for preventive treatment of migraine **AND** - Documentation that medication will not be concurrently used with botulinum toxin **OR** if being used with botulinum toxin, documentation of therapeutic failure on at least 3-month trial with at least one CGRP antagonist without Botox **AND** documentation of failure of a minimum 6-month trial of Botox without a CGRP antagonist	**Nurtec Policy 629.0** - Prescribed by or in consultation with neurologist or headache specialist **AND** - Documentation that patient is 18 years of age or older **AND** - Diagnosis of migraine with or without aura based on ICHD-3 criteria **AND** - Documentation of number of baseline monthly migraine or headache days **AND** - Documentation of diagnosis of episodic migraine (≤14 headache days per month) **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least ~~three~~ two of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to Aimovig and Emgality **AND** - Documentation that medication will not be used with another CGRP antagonist indicated for preventive treatment of migraine **AND** - Documentation that medication will not be concurrently used with botulinum toxin **OR** if being used with botulinum toxin, documentation of therapeutic failure on at least 3-month trial with at least one CGRP antagonist without Botox **AND** documentation of failure of a minimum 6-month trial of Botox without a CGRP antagonist
Qulipta (atogepant)	**Qulipta Policy 696.0** - Prescribed by or in consultation with neurologist or headache specialist **AND** - Documentation that patient is 18 years of age or older **AND** - Diagnosis of migraine with or without aura based on ICHD-3 criteria **AND** - Documentation of number of baseline monthly migraine or headache days **AND**	**Qulipta Policy 696.0** - Prescribed by or in consultation with neurologist or headache specialist **AND** - Documentation that patient is 18 years of age or older **AND** - Diagnosis of migraine with or without aura based on ICHD-3 criteria **AND** - Documentation of number of baseline monthly migraine or headache days **AND**

	- Documentation of diagnosis of episodic migraine (≥14 headache days per month) **AND** - Documentation that medication will not be used with another CGRP antagonist indicated for preventive treatment of migraine **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least three of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to Aimovig and Emgality **AND** - Documentation that medication will not be concurrently used with botulinum toxin **OR** if being used with botulinum toxin, documentation of therapeutic failure on at least 3-month trial with at least one CGRP antagonist without Botox **AND** documentation of failure of a minimum 6-month trial of Botox without a CGRP antagonist	- Documentation of diagnosis of episodic migraine (≥14 headache days per month) **AND** - Documentation that medication will not be used with another CGRP antagonist indicated for preventive treatment of migraine **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least ~~three~~ two of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to Aimovig and Emgality **AND** - Documentation that medication will not be concurrently used with botulinum toxin **OR** if being used with botulinum toxin, documentation of therapeutic failure on at least 3-month trial with at least one CGRP antagonist without Botox **AND** documentation of failure of a minimum 6-month trial of Botox without a CGRP antagonist
Vyepti (eptinezumab-jjmr)	**Vyepti MBP 218.0** - Prescription written by or in consultation with a neurologist or headache specialist **AND** - Medical record documentation of the patient age greater than or equal to 18 years **AND** - Medical record documentation of a diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria **AND** - Medical record documentation of the number of baseline migraine or headache days per month **AND** - Medical record documentation of the patient experiencing 4 or more migraines per month **AND** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Aimovig and Emgality **AND** - If the request is for Vyepti 300mg every 3 months, medical record documentation of	**No changes recommended**

	therapeutic failure on Vyepti 100mg every 3 months **AND**
	- If the request is for use in combination with Botox, all of the following must be met:
	  o Medical record documentation of therapeutic failure on a minimum 3 month trial of at least one calcitonin gene-related peptide (CGRP) receptor antagonist without the concomitant use of Botox **AND**
	  o Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of calcitonin gene-related peptide (CGRP) receptor antagonist **AND**
	- Medical record documentation that Vyepti will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventative treatment of migraine (e.g. Aimovig, Ajovy, Emgality, Nurtec ODT, Qulipta).	

Botox (onabotulinumtoxinA)	**Botox Policy MBP 11.0** - Documentation of history of 15 or more migraine days per month lasting 4 or more hours per day **AND** - Prescribed by or in consultation with a neurologist or headache specialist **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least three of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation that medication will not be used in combination with a CGRP antagonist **OR** - If request is for used in combination with CGRP antagonist, must provide documentation of therapeutic failure on minimum 3 month trial of at least one CGRP antagonist without concomitant use of Botox **AND** documentation of therapeutic failure on minimum of 6 month trial of Botox without concomitant use of CGRP antagonist	**Botox Policy MBP 11.0** - Documentation of history of 15 or more migraine days per month lasting 4 or more hours per day **AND** - Prescribed by or in consultation with a neurologist or headache specialist **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least ~~three~~ two of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation that medication will not be used in combination with a CGRP antagonist **OR** - If request is for used in combination with CGRP antagonist, must provide documentation of therapeutic failure on minimum 3 month trial of at least one CGRP antagonist without concomitant use of Botox **AND** documentation of therapeutic failure on minimum of 6 month trial of Botox without concomitant use of CGRP antagonist

Financial Recommendation: Recommend moving Aimovig and Emgality to non-preferred brand tier.

Commercial (Traditional)/ Exchange (Marketplace)/ CHIP (Kids)		
Medication	**Current Policy**	**Recommendations**
Aimovig (erenumab-aooe)	**Aimovig Policy 511.0** - Prescribed by or in consultation with neurologist or headache specialist **AND** - Documentation that patient is 18 years of age or older **AND** - Diagnosis of migraine with or without aura based on ICHD-3 criteria **AND** - Documentation of number of baseline monthly migraine or headache days **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least two of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation that medication will not be used with another CGRP antagonist indicated for preventive treatment of migraine **AND** - Documentation that medication will not be concurrently used with botulinum toxin **OR** if being used with botulinum toxin, documentation of therapeutic failure on at least 3-month trial with at least one CGRP antagonist without Botox **AND** documentation of failure of a minimum 6-month trial of Botox without a CGRP antagonist.	**Aimovig Policy 511.0** - ~~Prescribed by or in consultation with neurologist or headache specialist **AND**~~ - Documentation that patient is 18 years of age or older **AND** - Diagnosis of migraine with or without aura ~~based on ICHD-3 criteria~~ **AND** - Documentation of number of baseline monthly migraine or headache days **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least two of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation that medication will not be used with another CGRP antagonist indicated for preventive treatment of migraine **AND** - Documentation that medication will not be concurrently used with botulinum toxin **OR** if being used with botulinum toxin, documentation of therapeutic failure on at least 3-month trial with at least one CGRP antagonist without Botox **AND** documentation of failure of a minimum 6-month trial of Botox without a CGRP antagonist.
Ajovy (fremanezumab-vfrm)	**Ajovy Policy 532.0** - Prescribed by or in consultation with neurologist or headache specialist **AND** - Documentation that patient is 18 years of age or older **AND** - Diagnosis of migraine with or without aura based on ICHD-3 criteria **AND** - Documentation of number of baseline monthly migraine or headache days **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least three of the following: one beta-blocker	**Ajovy Policy 532.0** - ~~Prescribed by or in consultation with neurologist or headache specialist **AND**~~ - Documentation that patient is 18 years of age or older **AND** - Diagnosis of migraine with or without aura ~~based on ICHD-3 criteria~~ **AND** - Documentation of number of baseline monthly migraine or headache days **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least ~~three~~ two of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol,

Commented [EMA2]: All-commercial-policies-8-3-22.pdf (geisinger.org)

Formatted: Strikethrough, Highlight

Formatted: Strikethrough, Highlight

Formatted: Font: Not Bold

Formatted: Font color: Custom Color(RGB(66,66,66))

Formatted: Left, Space After: 0 pt, Don't add space between paragraphs of the same style, Line spacing: single, Bulleted + Level: 1 + Aligned at: 0.25" + Indent at: 0.5"

Formatted: Font: (Default) +Body (Arial), Font color: Custom Color(RGB(66,66,66))

Formatted: Strikethrough, Highlight

Formatted: Strikethrough, Highlight

Formatted: Strikethrough

Formatted: Not Highlight

	(metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to Aimovig and Emgality **AND** - Documentation that medication will not be used with another CGRP antagonist indicated for preventive treatment of migraine **AND** - Documentation that medication will not be concurrently used with botulinum toxin **OR** if being used with botulinum toxin, documentation of therapeutic failure on at least 3-month trial with at least one CGRP antagonist without Botox **AND** documentation of failure of a minimum 6-month trial of Botox without a CGRP antagonist	nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to two of the following: Aimovig, Emgality, and Nurtec ODT **AND** - Documentation that medication will not be used with another CGRP antagonist indicated for preventive treatment of migraine **AND** - Documentation that medication will not be concurrently used with botulinum toxin **OR** if being used with botulinum toxin, documentation of therapeutic failure on at least 3-month trial with at least one CGRP antagonist without Botox **AND** documentation of failure of a minimum 6-month trial of Botox without a CGRP antagonist
Emgality (galcanezumab-gnlm)	**Emgality Policy 533.0** - Prescribed by or in consultation with neurologist or headache specialist **AND** - Documentation that patient is 18 years of age or older **AND** - Diagnosis of migraine with or without aura based on ICHD-3 criteria **AND** - Documentation of number of baseline monthly migraine or headache days **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least two of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation that medication will not be used with another CGRP antagonist indicated for preventive treatment of migraine **AND** - Documentation that medication will not be concurrently used with botulinum toxin **OR** if being used with botulinum toxin, documentation of therapeutic failure on at least 3-month trial with at least one CGRP antagonist without Botox **AND** documentation of failure of a minimum 6-month trial of Botox without a CGRP antagonist	**Emgality Policy 533.0** - ~~Prescribed by or in consultation with neurologist or headache specialist **AND**~~ - Documentation that patient is 18 years of age or older **AND** - Diagnosis of migraine with or without aura ~~based on ICHD-3 criteria~~ **AND** - Documentation of number of baseline monthly migraine or headache days **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least two of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation that medication will not be used with another CGRP antagonist indicated for preventive treatment of migraine **AND** - Documentation that medication will not be concurrently used with botulinum toxin **OR** if being used with botulinum toxin, documentation of therapeutic failure on at least 3-month trial with at least one CGRP antagonist without Botox **AND** documentation of failure of a minimum 6-month trial of Botox without a CGRP antagonist

Formatted: Font: Not Bold

Formatted: Highlight

Formatted: Highlight

Formatted: Highlight

Formatted: Highlight

Formatted: Strikethrough, Highlight

Formatted: Strikethrough, Highlight

Formatted: Strikethrough

Formatted: Font: Not Bold

Formatted: Font color: Custom Color(RGB(66,66,66))

Formatted: Left, Space After: 0 pt, Don't add space between paragraphs of the same style, Line spacing: single, Bulleted + Level: 1 + Aligned at: 0.25" + Indent at: 0.5"

Formatted: Font: (Default) +Body (Arial), Bold, Font color: Custom Color(RGB(66,66,66))

Nurtec ODT (rimegepant)	**Nurtec Policy 629.0** - Prescribed by or in consultation with neurologist or headache specialist **AND** - Documentation that patient is 18 years of age or older **AND** - Diagnosis of migraine with or without aura based on ICHD-3 criteria **AND** - Documentation of number of baseline monthly migraine or headache days **AND** - Documentation of diagnosis of episodic migraine (≤14 headache days per month) **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least three of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to Aimovig and Emgality **AND** - Documentation that medication will not be used with another CGRP antagonist indicated for preventive treatment of migraine **AND** - Documentation that medication will not be concurrently used with botulinum toxin **OR** if being used with botulinum toxin, documentation of therapeutic failure on at least 3-month trial with at least one CGRP antagonist without Botox **AND** documentation of failure of a minimum 6-month trial of Botox without a CGRP antagonist	**Nurtec Policy 629.0** - ~~Prescribed by or in consultation with neurologist or headache specialist **AND**~~ - Documentation that patient is 18 years of age or older **AND** - Diagnosis of migraine with or without aura ~~based on ICHD-3 criteria~~ **AND** - Documentation of number of baseline monthly migraine or headache days **AND** - Documentation of diagnosis of episodic migraine (≤14 headache days per month) **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least ~~three~~ two of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - ~~Documentation of therapeutic failure on, intolerance to, or contraindication to Aimovig and Emgality **AND**~~ - Documentation that medication will not be used with another CGRP antagonist indicated for preventive treatment of migraine **AND** - Documentation that medication will not be concurrently used with botulinum toxin **OR** if being used with botulinum toxin, documentation of therapeutic failure on at least 3-month trial with at least one CGRP antagonist without Botox **AND** documentation of failure of a minimum 6-month trial of Botox without a CGRP antagonist
Qulipta (atogepant)	**Qulipta Policy 696.0** - Prescribed by or in consultation with neurologist or headache specialist **AND** - Documentation that patient is 18 years of age or older **AND** - Diagnosis of migraine with or without aura based on ICHD-3 criteria **AND** - Documentation of number of baseline monthly migraine or headache days **AND** - Documentation of diagnosis of episodic migraine (≥14 headache days per month) **AND**	**Qulipta Policy 696.0** - ~~Prescribed by or in consultation with neurologist or headache specialist **AND**~~ - Documentation that patient is 18 years of age or older **AND** - Diagnosis of migraine with or without aura ~~based on ICHD-3 criteria~~ **AND** - Documentation of number of baseline monthly migraine or headache days **AND** - Documentation of diagnosis of episodic migraine (≥14 headache days per month) **AND**

Formatted: Strikethrough, Highlight

Formatted: Strikethrough, Highlight

Formatted: Strikethrough

Formatted: Strikethrough, Highlight

Formatted: Strikethrough, Highlight

Formatted: Strikethrough, Highlight

	- Documentation that medication will not be used with another CGRP antagonist indicated for preventive treatment of migraine **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least three of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to Aimovig and Emgality **AND** - Documentation that medication will not be concurrently used with botulinum toxin **OR** if being used with botulinum toxin, documentation of therapeutic failure on at least 3-month trial with at least one CGRP antagonist without Botox **AND** documentation of failure of a minimum 6-month trial of Botox without a CGRP antagonist	- Documentation that medication will not be used with another CGRP antagonist indicated for preventive treatment of migraine **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least ~~three~~ two of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to two of the following: Aimovig, Emgality and Nurtec ODT **AND** - Documentation that medication will not be concurrently used with botulinum toxin **OR** if being used with botulinum toxin, documentation of therapeutic failure on at least 3-month trial with at least one CGRP antagonist without Botox **AND** documentation of failure of a minimum 6-month trial of Botox without a CGRP antagonist
Vyepti (eptinezumab-jjmr)	**Vyepti MBP 218.0** - Prescription written by or in consultation with a neurologist or headache specialist **AND** - Medical record documentation of the patient age greater than or equal to 18 years **AND** - Medical record documentation of a diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria **AND** - Medical record documentation of the number of baseline migraine or headache days per month **AND** - Medical record documentation of the patient experiencing 4 or more migraines per month **AND** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Aimovig and Emgality **AND** - If the request is for Vyepti 300mg every 3 months, medical record documentation of therapeutic failure on Vyepti 100mg every 3 months **AND** - If the request is for use in combination with Botox, all of the following must be met:	**Vyepti MBP 218.0** - ~~Prescription written by or in consultation with a neurologist or headache specialist **AND**~~ - Medical record documentation of the patient age greater than or equal to 18 years **AND** - Medical record documentation of a diagnosis of migraine with or without aura~~, based on the ICHD-III diagnostic criteria~~ **AND** - Medical record documentation of the number of baseline migraine or headache days per month **AND** - Medical record documentation of the patient experiencing 4 or more migraines per month **AND** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two of the following: Aimovig, Emgality and Nurtec ODT **AND** - If the request is for Vyepti 300mg every 3 months, medical record documentation of therapeutic failure on Vyepti 100mg every 3 months **AND** - If the request is for use in combination with Botox, all of the following must be met: o Medical record documentation of therapeutic failure on a minimum 3 month trial of at least one calcitonin gene-related peptide (CGRP)

Formatted: Font: Not Bold

Formatted: Highlight

Formatted: Highlight

Formatted: Highlight

Formatted: Highlight

Formatted: Left, Space After: 0 pt, Don't add space between paragraphs of the same style, Line spacing: single, Bulleted + Level: 1 + Aligned at: 0.25" + Indent at: 0.5"

Formatted: Normal, Don't add space between paragraphs of the same style, Bulleted + Level: 1 + Aligned at: 0.25" + Indent at: 0.5"

Formatted: Font: (Default) +Body (Arial), Font color: Custom Color(RGB(66,66,66))

Formatted: Strikethrough, Highlight

Formatted: Normal, Don't add space between paragraphs of the same style, Bulleted + Level: 1 + Aligned at: 0.25" + Indent at: 0.5"

Formatted: Strikethrough, Highlight

Formatted: Highlight

Formatted: Highlight

Formatted: Highlight

Formatted: Highlight

Formatted: Font: Not Bold

Formatted: Normal, Don't add space between paragraphs of the same style, Bulleted + Level: 1 + Aligned at: 0.25" + Indent at: 0.5"

Formatted: Normal, Don't add space between paragraphs of the same style, Bulleted + Level: 2 + Aligned at: 0.75" + Indent at: 1"

	○ Medical record documentation of therapeutic failure on a minimum 3 month trial of at least one calcitonin gene-related peptide (CGRP) receptor antagonist without the concomitant use of Botox **AND** ○ Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of calcitonin gene-related peptide (CGRP) receptor antagonist **AND** - Medical record documentation that Vyepti will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventative treatment of migraine (e.g. Aimovig, Ajovy, Emgality, Nurtec ODT, Qulipta).	receptor antagonist without the concomitant use of Botox **AND** ○ Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of calcitonin gene-related peptide (CGRP) receptor antagonist **AND** - Medical record documentation that Vyepti will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventative treatment of migraine (e.g. Aimovig, Ajovy, Emgality, Nurtec ODT, Qulipta).
Botox (onabotulinumtoxinA)	**Botox Policy MBP 11.0** - Documentation of history of 15 or more migraine days per month lasting 4 or more hours per day **AND** - Prescribed by or in consultation with a neurologist or headache specialist **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least three of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation that medication will not be used in combination with a CGRP antagonist **OR** - If request is for used in combination with CGRP antagonist, must provide documentation of therapeutic failure on minimum 3 month trial of at least one CGRP antagonist without concomitant use of Botox **AND** documentation of therapeutic failure on minimum of 6 month trial of Botox without concomitant use of CGRP antagonist	**Botox Policy MBP 11.0** - Documentation of history of 15 or more migraine days per month lasting 4 or more hours per day **AND** - Prescribed by or in consultation with a neurologist or headache specialist **AND** - Documentation of therapeutic failure on, intolerance to, or contraindication to at least ~~three~~ two of the following: one beta-blocker (metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine **AND** - Documentation that medication will not be used in combination with a CGRP antagonist **OR** - If request is for used in combination with CGRP antagonist, must provide documentation of therapeutic failure on minimum 3 month trial of at least one CGRP antagonist without concomitant use of Botox **AND** documentation of therapeutic failure on minimum of 6 month trial of Botox without concomitant use of CGRP antagonist

Formatted: Normal, Left, Don't add space between paragraphs of the same style, Bulleted + Level: 1 + Aligned at: 0.25" + Indent at: 0.5"

Formatted: Space After: 0 pt, Don't add space between paragraphs of the same style, Line spacing: single, Bulleted + Level: 1 + Aligned at: 0.25" + Indent at: 0.5"

Formatted: Font: (Default) +Body (Arial), Bold, Font color: Custom Color(RGB(66,66,66))

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Fast Facts

ADCETRIS (brentuximab vedotin)

Updated Indication: Adcetris is a CD30-directed antibody-drug conjugate that is now indicated for the treatment of previously untreated high risk classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide in pediatric patients aged 2 years and older. Previously, Adcetris was indicated for the treatment of previously untreated Stage III or IV cHL in combination with doxorubicin, vinblastine, and dacarbazine, cHL at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation, cHL after failure of auto-HSCT or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates, previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, in combination with cyclophosphamide, doxorubicin, and prednisone, sALCL after failure of at least one prior multi-agent chemotherapy regimen, and primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy.

Current formulary status: Medical benefit requiring prior authorization. When processed at a specialty pharmacy, it is on the specialty tier or brand non preferred tier.

Recommendation: No changes are recommended to the formulary placement of Adcetris. It is recommended that the following prior authorization criteria be added to the Medical Benefit Policy 166.0 to incorporate the updated indication:

Classical Hodgkin Lymphoma (cHL)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is at least 18 years of age **AND**
- Medical record documentation of a diagnosis of classical Hodgkin Lymphoma meeting one of the following situations:
  - Medical record documentation that patient is at least 18 years of age **AND**
  - Medical record documentation of failure of autologous hematopoietic stem cell transplant (auto-HSCT)

  OR
  - Medical record documentation that patient is at least 18 years of age **AND**
  - Medical record documentation of failure of at least 2 multi-agent chemotherapy regimens in patients who are not candidates for auto-HSCT

  OR
  - Medical record documentation that patient is at least 18 years of age **AND**
  - Medical record documentation of use as consolidation treatment following auto-HSCT in patients with high risk of relapse or progression post-auto-HSCT (high risk patients include: refractory to first line therapy, relapse within 12 months of first line therapy, presence of extranodal disease)

  OR
  - Medical record documentation that patient is at least 18 years of age **AND**
  - Medical record documentation of previously untreated Stage III or IV cHL **AND**
  - Medical record documentation that Adcetris will be used in combination with doxorubicin, vinblastine, and dacarbazine.

  OR
  - Medical record documentation that patient is at least 2 years of age **AND**
  - Medical record documentation of previously untreated high risk cHL **AND**
  - Medical record documentation that Adcetris will be used in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide

AUTHORIZATION DURATION:

Indication	Initial Authorization	Subsequent Authorizations
Previously Untreated Stage III or IV cHL	Initial approval will be limited to 12 doses (6 months) or less if the reviewing provider feels it is medically appropriate.	Subsequent approval for treatment past the initial 12 doses will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.
cHL Consolidation	Initial approval will be limited to 6 months or less if the reviewing provider feels it is medically appropriate.	Subsequent approval will be for one additional 6-month authorization to allow for a total of 16 cycles of treatment.
Relapsed pcALCL or CD30-expressing MF		Subsequent approval for treatment past 16 cycles will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.
Previously Untreated sALCL or Other CD30-expressing PTCLs	Initial approval will be limited to 8 doses (6 months) or less if the reviewing provider feels it is medically appropriate.	Subsequent approval for treatment past the initial 8 doses will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.
Relapsed cHL **Relapsed sALCL**	Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate.	Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. Adcetris will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.
Previously Untreated high risk cHL in pediatric patients	Initial approval will be limited to 5 doses (15 weeks) or less if the reviewing provider feels it is medically appropriate	Subsequent approval for treatment past the initial 5 doses will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

BENLYSTA (belimumab)

Updated Indication: Benlysta is now indicated for the treatment of patients aged 5 years and older with active lupus nephritis (LN) who are receiving standard therapy. Previously, it was indicated in adult patients with active LN who were receiving standard therapy, and in patients 5 years and older with active, antibody-positive systemic lupus erythematosus (SLE) who were receiving standard therapy.

Current formulary status: Benlysta autoinjector/prefilled syringes are a pharmacy benefit available at the Specialty tier or the Brand Non-Preferred (NP) tier for members with a three tier benefit. Benlysta vials are a medical benefit. If processed through a specialty pharmacy, Benlysta vials will process at Specialty tier or the Brand NP tier for members with a three tier benefit. Benlysta requires a prior authorization.

Recommendation: There are no recommended changes to formulary status, auth duration, or quantity limits at this time. It is recommended to edit LN criteria for the following Benlysta policies to include the updated population for Commercial Policy 475.0.

It is also recommended to update the prior authorization criteria under SLE for Commercial Policy 475.0 to more closely align to the FDA-approved indication and to include additional clinical scenarios in which Benlysta may be initiated in SLE.

Systemic Lupus Erythematosus (SLE)

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of ~~active~~ systemic lupus erythematosus **AND**
- Medical record documentation that patient has active disease OR recurrent flares OR inability to wean steroids in systemic lupus erythematosus **AND**
- Medical record documentation that Benlysta for self-administration is prescribed by a rheumatologist **AND**
- Medical record documentation of a positive ANA/anti-~~sd~~ dsDNA antibody **AND**
- ~~Medical record documentation that member is concurrently receiving a stable treatment regimen with prednisone, an NSAID, anti-malarial or immunosuppressant **AND**~~ Medical record documentation that Benlysta is being used in combination with, or patient has a contraindication or intolerance to, standard therapy (e.g. corticosteroid, NSAID, anti-malarial or immunosuppressant) **AND**
- Medical record documentation of no central nervous system (CNS) involvement

Lupus Nephritis (LN)

- Medical record documentation of a diagnosis of active lupus nephritis, Class III, IV, V alone or in combination, confirmed by a kidney biopsy **AND**
- Medical record documentation of age greater than or equal to ~~18 years~~ 5 years **AND**
- Medical record documentation that Benlysta for self-administration is prescribed by or in consultation with a rheumatologist or nephrologist **AND**
- Medical record documentation that Benlysta will be prescribed in combination with standard therapy (e.g., mycophenolate mofetil (MMF), corticosteroids, cyclophosphamide, azathioprine)

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

COTELLIC (cobimetinib)

Updated Indication: Cotellic is now indicated for histiocytic neoplasms. Previously, Cotellic was approved for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib.

Histiocytic neoplasms are rare hematologic disorders accounting for less than 1% of cancers of the soft tissue and lymph nodes. Clinical presentation and prognosis of these disorders can be highly variable, leading to challenges in diagnosis and optimal management for patients. Treatment often consists of systemic therapy and recent studies support use of targeted therapies for patients with these disorders. Observation may be sufficient for select patients with mild disease.

Current formulary status: Cotellic is a pharmacy benefit on specialty tier or brand non-preferred tier for members with a three- tier benefit, requiring prior authorization with a quantity limit of 3 tabs per day, 30- day supply per fill.

- Medical record documentation that Cotellic is prescribed by a hematologist, oncologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of unresectable or metastatic melanoma **AND**
- Medical record documentation of BRAF V600E or V600K mutation as detected by aa Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation of concomitant use with Zelboraf (vemurafenib) **OR**
- Medical record documentation that Cotellic is prescribed by a hematologist, oncologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of histiocytic neoplasm (Langerhans Cell Histiocytosis, Rosai-Dorfman Disease, Erdheim-Chester Disease, Xanthogranuloma, Mixed Histiocytosis)

Recommendation: There are no changes recommended to formulary placement of Cotellic at this time. However, it is recommended to update the prior authorization criteria in the current policy to include the following:

Discussion: No comments or questions

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

ORKAMBI (ivacaftor/lumacaftor)

Clinical Summary: Orkambi is indicated for the treatment of cystic fibrosis (CF) in patients aged 1 year and older who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene.

Previously, Orkambi was only indicated in patients aged 2 years and older.

Current formulary status: Orkambi is a pharmacy benefit available at the Specialty tier or the Brand Non-Preferred tier for members with a three-tier benefit. Orkambi requires a prior authorization.

Recommendation: The 75/94 mg strength packet should be added to the formulary at the Specialty tier or Brand non-preferred tier for members with a 3-tier benefit and will require a prior authorization. There are no changes to the formulary status for other strengths of Orkambi already on the formulary. However, it is recommended to update the age restriction to the following:

"…Medical record documentation of patient age greater than or equal to 1 years AND"

QUANTITY LIMIT: No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.

- QL FOR LETTER ONLY:
  - 4 tablets per day, 30 day supply per fill
  - 2 packets per day, 28 day supply per fill

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

IMBRUVICA (ibrutinib)

Updated Indication: Imbruvica is now indicated for the treatment of adult and pediatric patients 1 year of age and older with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy. Imbruvica was previously indicated for the following:

- treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy
  - This indication was approved under accelerated approved based on overall response rate.
- treatment of adult patients with chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL)
- treatment of adult patients with chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion
- treatment of adult patients with Waldenström's macroglobulinemia (WM)
- treatment of adult patients with marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy
  - This indication was approved under accelerated approved based on overall response rate.
- treatment of adult patients with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy

There is now an oral suspension formulation of Imbruvica.

Current Formulary Status: Imbruvica is a pharmacy benefit requiring a prior authorization with a quantity limit. It is on the oral oncology brand non-preferred tier ($0 copay).

Recommendation: No changes recommended to the formulary placement or authorization duration of Imbruvica at this time. However, it is recommended to update policy 315.0 to include the following highlighted changes.

Chronic Graft Versus Host Disease (cGVHD)

- Medical record documentation that Imbruvica is prescribed by a hematologist or oncologist AND
- Medical record documentation of chronic graft versus host disease AND
- Medical record documentation of age greater than or equal to 1 year AND
- Medical record documentation of therapeutic failure on one or more lines of systemic therapy AND
- Medical record documentation that the member is receiving an appropriate dose** based on the patient's age and body surface area (BSA)

**Note: Recommended dosage for cGVHD:
Patients 12 years of age and older: 420mg orally once daily
Pediatric patients 1 to less than 12 years of age to achieve 240 mg/m^2 orally once daily:

BSA(m^2) Range	Dose (mg) of Imbruvica	Dose of Imbruciva Oral

	Capsules/Tablets to Administer	Suspension (70 mg/mL) to Administer
>0.3 to 0.4	-	84mg OR 1.2mL
>0.4 to 0.5	-	105mg OR1.5mL
>0.5 to 0.6	-	133mg OR 1.9mL
>0.6 to 0.7	-	154mg OR 2.2mL
>0.7 to 0.8	210mg	182mg OR 2.6mL
>0.8 to 0.9	210mg	203mg OR 2.9mL
>0.9 to 1.0	210mg	231mg OR 3.3mL
>1.0 to 1.1	280mg	252mg OR 3.6mL
>1.1 to 1.2	280mg	280mg OR 4.0mL
>1.2 to 1.3	280mg	301mg OR 4.3mL
>1.3 to 1.4	350mg	322mg OR 4.6mL
>1.4 to 1.5	350mg	350mg OR 5.0mL
>1.5 to 1.6	350mg	371mg OR 5.3mL
>1.6	420mg	420mg OR 6.0mL

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
QL FOR LETTER ONLY:

- Capsules: 1 capsule per day, 28 day supply per fill
- Tablets: 1 tablet per day, 28 day supply per fill
- Oral Suspension: 6mL per day, maximum 36 day supply per fill

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

LIBTAYO (cemiplimab-rwlc)

Updated Indication: Libtayo is now indicated for Non-Small Cell Lung Cancer (NSCLC) used in combination with platinum-based chemotherapy for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) with no EGFR, ALK or ROS1 aberrations and is locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or metastatic.

Current formulary status: Libtayo is currently a medical benefit medication under MBP policy 186.0 requiring prior authorization.

Recommendation: Recommend the following addition to the prior authorization criteria for the Libtayo MBP 186.0.

Non-Small Cell Lung Cancer (NSCLC)

- Prescription written by a hematologist or oncologist **AND**
- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of non-small cell lung cancer (NSCLC) **AND** medical record documentation of one of the following:

- Documentation of locally advanced disease AND the patient is not a candidate for surgical resection or definitive chemoradiation **OR**
- Documentation of metastatic disease

AND

- ~~Medical record documentation of high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%] as determined by an FDA-approved test **AND**~~
- Medical record documentation of no EGFR, ALK, or ROS1 genomic tumor aberrations **AND**
- Medical record documentation that Libtayo is being used as first-line treatment **AND**
- Medical record documentation of one of the following situations being met:
  - Libtayo is being used as a single agent **AND**
  - High PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%] as determined by an FDA-approved test

  OR
  - Libtayo is being used in combination with platinum-based chemotherapy

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

MYFEMBREE (relugolix, estradiol, and norethindrone acetate)

Updated Indication: Myfembree is now indicated for the management of moderate to severe pain associated with endometriosis. Previously, Myfembree was indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids).

Current formulary status: Pharmacy benefit at the Specialty tier or brand Non-Preferred tier for members with a three tier benefit. Myfembree requires a prior authorization.

Recommendation: There are no changes recommended to the formulary placement or auth duration for Myfembree. The following changes are recommended to the prior authorization criteria in Commercial Policy 684.0:

Endometriosis, moderate to severe pain:

- Medical record documentation that Myfembree is prescribed by a gynecologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that patient is premenopausal **AND**
- Medical record documentation of a diagnosis of moderate to severe pain associated with endometriosis **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to one formulary extended-cycle contraceptive **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two formulary nonsteroidal anti-inflammatory drugs (NSAIDs)

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

OPZELURA (ruxolitinib)

Updated Indication: Opzelura is now indicated for the treatment of nonsegmental vitiligo in adult and pediatric patients 12 years and older. Previously, it was approved for treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 12 years and older.

Current formulary status: Pharmacy benefit on the brand non-preferred tier requiring prior authorization.

Recommendation: No formulary placement or prior authorization criteria changes are recommended at this time. Vitiligo is an excluded diagnosis.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

RINVOQ (upadacitinib)

Updated Indication: Rinvoq is now approved for adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy. Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.

Current formulary status: Rinvoq is a pharmacy benefit on Specialty tier (or Brand Non-preferred tier for members with a three tier benefit) requiring a prior authorization with a quantity limit of 1 tablet per day.

Recommendation: There are no changes recommended to the formulary placement or authorization duration, or quantity limit at this time. The following prior authorization criteria should be added to the Rinvoq policy:

Non-radiographic Axial Spondylarthritis

- Medical record documentation that Rinvoq is written by a rheumatologist **AND**
- Medical record documentation of age 18 years or older **AND**
- Medical record documentation of non-radiographic axial spondylarthritis **AND**
- Medical record documentation of at least one of the following:
    - C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) **OR**
    - Sacroiliitis on magnetic resonance imaging (MRI)

AND

- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on one (1) preferred tumor necrosis factor (TNF) blocker **AND**
- Medical record documentation that Rinvoq is not being used concurrently with a TNF blocker or other biologic agent

Quantity Limit: 1 tablet per day

MEDISPAN AUTHORIZATION LEVEL: GPI-12

RE-AUTHORIZATION CRITERIA: Rinvoq is configured as a prior authorization for new starts only. Rinvoq will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90-day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist is required.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

STELARA (ustekinumab)

Updated Indication: Stelara® (ustekinumab) is a fully humanized immunoglobulin G1 monoclonal antibody that targets the p40 subunit of human IL-12 and IL-23. Stelara®, as of July 2022, received FDA approval for use in patients 6 years of age and older with active psoriatic arthritis.

Current formulary status: Pharmacy or medical benefit requiring prior authorization; for pharmacy benefit - specialty tier or brand non preferred for members with a 3 tier benefit.

Recommendation: There are no changes recommended to the formulary placement or auth duration of Stelara. The following changes are recommended to the prior authorization criteria in Medical Benefit Policy 75.0 and Commercial Policy 318.0:

For Psoriatic Arthritis

- Medical record documentation that Stelara is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
    - Documentation of either active psoriatic lesions or a documented history of psoriasis AND
- Medical record documentation of an inadequate response to, contraindication to, or failure on at least 3 months ~~Cosentyx® AND Humira®~~ of three (3) preferred formulary biologics for the treatment of psoriatic arthritis

  (Note for pediatric PsA/JIA treatment under <18 years of age, only Cosentyx, Humira and Enbrel have FDA approval)

- Medical record documentation that the patient is going to receive a dose of 45 mg every 12 weeks OR medical record documentation that the patients has a co-existing diagnosis of moderate-to-severe plaque psoriasis and weight greater than 100 kg OR member is under the age of 18 years old and is receiving the recommended weight based dose AND

- Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

*****Note to reviewer - pediatric PsA is a category of juvenile idiopathic arthritis (JIA)**

Formulary Alternatives:
Enbrel, Humira, Otezla, Skyrizi, Tremfya, Cosentyx, Rinvoq, Xeljanz/XR, Cimzia, Orencia, Simponi

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

STELARA (ustekinumab)

Updated Indication: Stelara® (ustekinumab) is a fully humanized immunoglobulin G1 monoclonal antibody that targets the p40 subunit of human IL-12 and IL-23. Stelara®, as of July 2022, received FDA approval for use in patients 6 years of age and older with active psoriatic arthritis.

Current formulary status: Pharmacy or medical benefit requiring prior authorization; for pharmacy benefit - specialty tier or brand non preferred for members with a 3 tier benefit.

Recommendation: There are no changes recommended to the formulary placement or auth duration of Stelara. The following changes are recommended to the prior authorization criteria in Medical Benefit Policy 75.0 and Commercial Policy 318.0:

For Psoriatic Arthritis

- Medical record documentation that Stelara is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
    - Documentation of either active psoriatic lesions or a documented history of psoriasis AND
- Medical record documentation of an inadequate response to, contraindication to, or failure on at least 3 months ~~Cosentyx* AND Humira*~~ of three (3) preferred formulary biologics for the treatment of psoriatic arthritis

  (Note for pediatric PsA/JIA treatment under <18 years of age, only Cosentyx, Humira and Enbrel have FDA approval)

- Medical record documentation that the patient is going to receive a dose of 45 mg every 12 weeks OR medical record documentation that the patients has a co-existing diagnosis of moderate-to-severe plaque psoriasis and weight greater than 100 kg OR member is under the age of 18 years old and is receiving the recommended weight based dose AND
- Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

*****Note to reviewer - pediatric PsA is a category of juvenile idiopathic arthritis (JIA)**

Formulary Alternatives:
Enbrel, Humira, Otezla, Skyrizi, Tremfya, Cosentyx, Rinvoq, Xeljanz/XR, Cimzia, Orencia, Simponi

Updates to Medical Benefit Policy 75.0 Stelara (ustekinumab)
MBP 75.0 Stelara (ustekinumab)

Background: Stelara (subcutaneous) was originally approved by the Food and Drug Administration (FDA) in 2009. When it was originally approved by the FDA, it was approved for administration under the supervision of a physician. In May of 2013, the labeling of Stelara was updated to allow for patient self-administration after proper training if the supervising physician deems it appropriate and patient is closely monitored and have regular follow-up visits with the physician. In 2017, the labeling further relaxed related to self-administration to allow for self-administration as long as patients have regular monitoring and regular follow-up. This labeling is maintained today.

FDA approval of Stelara in the adolescent population was granted in 2017, and at that time the labeling required administration by a healthcare professional for the adolescent population. In 2018 this was updated to allow for self-administration or administration by family/caregiver after appropriate training. This labeling is maintained today.

Per CMS article A53127 (Self-Administered Drug Exclusion List), Stelara subcutaneous was added to the Self-Administered Drug Exclusion List effective 6/6/22 and is no longer reimbursable as a Part B benefit (buy and bill).

Recommendations: Based on the above information, Stelara subcutaneous is determined to be a self-administered benefit and should be excluded from coverage as a medical benefit and covered only as a pharmacy benefit. MBP 75.0 should be edited as follows as the policy will no longer apply to Stelara Subcutaneous.
Notable changes (complete changes outlined within policy):

- Removal of indications for which only subcutaneous formulation is indicated (PsA, & PsO)
- Removal of authorization of subcutaneous syringes via medical benefit for CD and UC.
- Removal of reauthorization criteria
- Formatting of policy to apply to intravenous formulation only

Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 75.0
Section: Medical Benefit Pharmaceutical Policy
Subject: Stelara IV (ustekinumab)

I. Policy:
Stelara IV (ustekinumab)

II. Purpose/Objective:
To provide a policy of coverage regarding Stelara IV (ustekinumab)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age

DESCRIPTION:
Stelara (ustekinumab) is a fully humanized immunoglobulin G1 monoclonal antibody that targets the p40 subunit of human IL-12 and IL-23.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Stelara IV (ustekinumab) will be considered medically necessary when all of the following criteria are met:

1. **Adult Plaque Psoriasis**
   - Prescription must be written by a dermatologist **AND**
   - Member must be at least 18 years of age **AND**
   - Medical record documentation that the prescribed dosing is appropriate for patient's weight **AND**
   - Medical record documentation of moderate to severe plaque psoriasis characterized by ≥5% of body surface area involved or disease affecting crucial body areas such as the hands, feet, face, or genitals **AND**
   - Medical record documentation that Stelara is not being used concurrently with a TNF blocker or other biologic agent **AND**
   - Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx*

     *Requires Prior Authorization

2. **Pediatric Plaque Psoriasis**
   - Prescription must be written by a dermatologist **AND**
   - Member must be at least 6 years of age **AND**
   - Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by ≥5% of body surface area involved or disease affecting crucial body areas such as hands, feet, face, or genitals **AND**
   - Medical record documentation of intolerance to, contraindication to, or therapeutic failure on at least two topical corticosteroids **AND**
   - Medical record documentation that the prescribed dose is appropriate for the patient's weight **AND**
   - Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

Dosing for plaque psoriasis:
- Patients weighing over 100kg should receive 90 mg every 12 weeks (GPI 9025058500E540)
- Patients weighing ≥60kg to ≤100kg should receive 45 mg every 12 weeks (GPI 90250585002020 or 9025058500E520)
- Patients weighing less than 60kg should receive 0.75mg/kg every 12 weeks (via single dose vial – GPI 90250585002020)

AUTHORIZATION DURATION:
Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of plaque psoriasis at six (6) months of Stelara therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of plaque psoriasis while on Stelara therapy.

Quantity Limit (for plaque psoriasis):

If requesting a dose for patient weight:	Initial 6 month authorization	Subsequent 12 month authorization
Less than 60 kg	**Facets RX Count**: 135 **Darwin QL**: One-time, one week authorization: 0.5 mL per 28 days by GPI 14 Remainder of 6 month authorization: 0.5 mL per 84 days by GPI 14	**Facets RX Count**: 225 **Darwin QL**: 0.5 mL per 84 days by GPI 14
Greater than or equal to 60 kg to 100 kg or less	**Facets RX Count**: 135 **Darwin QL**: One-time, one week authorization: 0.5 mL per 28 days by GPI 14 Remainder of 6 month authorization: 0.5 mL per 84 days by GPI 14	**Facets RX Count**: 225 **Darwin QL**: 0.5 mL per 84 days by GPI 14
Greater than 100 kg	**Facets RX Count**: 270 **Darwin QL**: One-time, one week authorization: 1 mL per 28 days by GPI 14 Remainder of 6 month authorization: 1 mL per 84 days by GPI 14	**Facets RX Count**: 450 **Darwin QL**: 1 mL per 84 days by GPI 14

3. Psoriatic Arthritis

- Prescription must be written by a rheumatologist or a dermatologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation that the patient is going to receive a dose of 45 mg every 12 weeks OR medical record documentation that the patient has a co-existing diagnosis of moderate-to-severe plaque psoriasis and weighs > 100 kg. **AND**
- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
    - Documentation of either active psoriatic lesions or a documented history of psoriasis

AND

- Medical record documentation that Stelara is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx*

*Requires Prior Authorization

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of psoriatic arthritis at six (6) months of Stelara therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of psoriatic arthritis while on Stelara therapy.

Quantity Limit (for psoriatic arthritis):

If requesting a dose for patient weight:	Initial 6 month authorization	Subsequent 12 month authorization
100 kg or less	**Facets RX Count**: 135 **Darwin QL**: One-time, one week authorization: 0.5 mL per 28 days by GPI 14 Remainder of 6 month authorization: 0.5 mL per 84 days by GPI 14	**Facets RX Count**: 225 **Darwin QL**: 0.5 mL per 84 days by GPI 14
Greater than 100 kg	**Facets RX Count**: 270 **Darwin QL**: One-time, one week authorization: 1 mL per 28 days by GPI 14 Remainder of 6 month authorization:	**Facets RX Count**: 450 **Darwin QL**: 1 mL per 84 days by GPI 14

	~~1 mL per 84 days by GPI 14~~	

4. **Crohn's Disease (CD)**
   - Prescription must be written by a gastroenterologist **AND**
   - Member must be at least 18 years of age **AND**
   - Medical record documentation of moderately to severely active Crohn's disease **AND**
   - Medical record documentation that Stelara is not being used concurrently with a TNF blocker or other biologic agent **AND**
   - Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of three (3) of the following medications: Humira*, Cimzia*, Entyvio*, infliximab (or biosimilar) *, or Tysabri* **AND**
   - Medical record documentation of Stelara 130mg vials as IV infusion (for induction therapy) ~~OR Stelara 90mg syringes (for maintenance therapy) being prescribed.~~

   *Requires Prior Authorization

   Note to reviewer: Stelara 45mg syringe is not indicated for use in Crohn's disease.

   AUTHORIZATION DURATION: Approval will be given for an initial authorization duration of **six (6) months**. ~~After the initial 6-month maintenance approval, subsequent approvals for coverage will be for a duration of **twelve (12) months** requiring medical record documentation of continued or sustained improvement in the signs and symptoms of Crohn's disease while on Stelara therapy~~.

   Quantity limit (for Crohn's disease):
   Initial Authorization:
   - One-time authorization:
     - Facets Rx Count: 520 (J3358 – Ustekinumab IV)
     - Darwin Quantity Limit: 104 mL per 56 days GPI 14 for Stelara 130 mg vial
   - ~~Remainder of initial authorization:~~
     - ~~Facets RX Count: 270 (J3357 – Ustekinumab SQ [if requested through medical])~~
     - Darwin Quantity limit: 1mL per 56 days GPI 14 for Stelara 90mg Syringe

   ~~**Subsequent Authorizations**~~:
   - ~~Facets RX Count: 630 (J3357 – Ustekinumab SQ [if requested through medical])~~
   - ~~Darwin Quantity limit: 1 mL per 56 days GPI 14 for Stelara 90mg Syringe~~

5. **Ulcerative Colitis**
   - Prescription must be written by a gastroenterologist **AND**
   - Member must be at least 18 years of age **AND**
   - Medical record documentation of moderately to severely active ulcerative colitis **AND**
   - Medical record documentation that Stelara is not being used concurrently with a TNF blocker or other biologic agent **AND**
   - Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of three (3) of the following medications: Humira*, Entyvio*, ~~and~~ infliximab (or biosimilar)*, Rinvoq*, Simponi*, and/or Xeljanz/Xeljanz XR **AND**
   - Medical record documentation of Stelara 130mg vials as IV infusion (for induction therapy) ~~OR Stelara 90mg syringes (for maintenance therapy) being prescribed.~~

   *Requires Prior Authorization

   Note to reviewer: Stelara 45mg syringe is not indicated for use in ulcerative colitis.

   AUTHORIZATION DURATION: Approval will be given for an initial authorization duration of six (**6) months**. ~~After the initial 6-month maintenance approval, subsequent approvals for coverage will be for a duration of twelve (**12) months** requiring medical record documentation of continued or sustained improvement in the signs and symptoms of ulcerative colitis while on Stelara therapy.~~

Quantity limit (for ulcerative colitis):
Initial Authorization:

- One-time authorization:
  - Facets Rx Count: 520 (J3358 – Ustekinumab IV)
  - Darwin Quantity Limit: 104 mL per 56 days GPI 14 for Stelara 130 mg vial
- ~~Remainder of initial authorization:~~
  - ~~Facets RX Count: 270 (J3357 – Ustekinumab SQ [if requested through medical])~~
  - Darwin Quantity limit: 1mL per 56 days GPI 14 for Stelara 90mg Syringe

~~**Subsequent Authorizations**:~~

- ~~Facets RX Count: 630 (J3357 – Ustekinumab SQ [if requested through medical])~~

~~Darwin Quantity limit: 1 mL per 56 days GPI~~

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

XOFLUZA (baloxavir marboxil)

Clinical Summary: Xofluza is now indicated for treatment of acute uncomplicated influenza in patients who have been symptomatic for no more than 48 hours and who are otherwise healthy adults and pediatric patients 5 years of age and older, or adults and pediatric patients 12 years of age and older who are at high-risk of developing influenza related complications. Xofluza is also indicated for post-exposure prophylaxis of influenza in persons 5 years of age and older following contact with an individual who has influenza.

Previously, Xofluza was not indicated in patients aged 5 to less than 12 years of age.

Current formulary status: Xofluza is a pharmacy benefit and is currently at tier 3. No prior authorization Criteria.

Recommendation: There are no changes recommended.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

UPDATES

AMVUTTRA UPDATE

Background: It is recommended to update the prior authorization criteria presented at November's P&T for Amvuttra to reflect the current Prior Authorization criteria for Onpattro and Tegsedi which addresses prior changes that were made to both of those policies in 2019 based on specialist feedback.

Recommendations: Amvuttra will be covered as a medical benefit for Commercial/Exchange/CHIP members. Amvuttra should be added to the medical benefit cost share list when processed on the medical benefit. If processed at a specialty pharmacy, Amvuttra should process at the Specialty tier or the Brand Non-preferred tier for members with a three-tier benefit. It is recommended that Amvuttra require a prior authorization to ensure appropriate utilization. The following prior authorization criteria should apply.

Prior Authorization Criteria:

- Prescription written by or in consultation with a neurologist, board-certified medical geneticist, or specialist with experience in the treatment of hereditary transthyretin-mediated amyloidosis (hATTR) AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of diagnosis of hereditary transthyretin-mediated amyloidosis as confirmed by genetic testing to confirm a pathogenic mutation in TTR AND one of the following:
  - Biopsy of tissue/organ to confirm amyloid presence OR
  - A clinical manifestation typical of hATTR (Neuropathy and/or CHF) without a better alternative explanation AND
- Medical record documentation of Amvuttra being used to treat polyneuropathy AND
- Medical record documentation of familial amyloid polyneuropathy (FAP) stage 1-2 and/or polyneuropathy disability score (PND) indicating the patient is not wheelchair bound or bedridden AND
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature AND
- Medical record documentation that Amvuttra will not be used in combination with other RNA interference treatment AND
- Medical record documentation that the member has been evaluated and treated by a contracted Center of Excellence in amyloidosis management

Note: Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).

Note:

FAP stage:

1-unimpairmend ambulation
2- assistance with ambulation
3- wheelchair-bound or bedridden

Polyneuropathy disability score:

I- preserved walking, sensory disturbances
II- impaired walking without need for stick/crutches
IIIa- walking with 1 stick/crutch
IIIb- walking with 2 sticks/crutches
IV-wheelchair-bound or bedridden

Polyneuropathy disability score (used in Neuro-TTR trial for Tegsedi):

I- preserved walking, sensory disturbances
II- impaired walking without need for stick/crutches

III- walking with 1 stick/crutch
IV- walking with 2 sticks/crutches
V-wheelchair-bound or bedridden

Authorization Duration: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if the member progresses to FAP stage 3 and/or polyneuropathy disability score indicating the patient is wheelchair-bound or bedridden.

Quantity Limit: 0.5 mL per 84 days to be coded in Darwin for claims processed through specialty vendor. Currently Amvuttra does not have a unique HCPCS code assigned to it and is billed with a miscellaneous Jcode when billed through medical. Alnylam Pharmaceuticals submitted an application to CMS in the 3rd quarter 2022 for a unique HCPCS code, these codes are expected to be released in January 2023. At that time a Facets RX count quantity limit should be added respective of the updated HCPCS code units to reflect a limitation of one 25mg (0.5ml) syringe every 3 months to policy quantity limit language.

GPI Level: 10
Require RPH Sign off: Yes
Site of Care Program: Yes

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

DACOGEN

Background: Dacogen (decitabine) is indicated for the treatment of myelodysplastic syndromes (MDS). The Dacogen policy currently requires failure of Vidaza before approval of Dacogen for the diagnosis of MDS. NCCN guidelines do not prefer one agent to be used over another when a patient has higher risk MDS and is a transplant candidate. In addition, the FDA prescribing information for Dacogen does not require failure of Vidaza within the indication. Therefore clinically, Vidaza is not required to be used prior to Dacogen use in MDS. A summary of the cost effectiveness of all agents is listed below. Cost analysis indicates that Vidaza and its generic, azacitidine, are more expensive then generically available Dacogen.

Regarding utilization, from 11/1/2019 to 11/26/2022, Dacogen was reviewed 21 times for prior authorization and was approved 95% of the time, meaning one (1) Dacogen prior authorization request was denied in the past three (3) years.

Recommendations: It is recommended to remove the prior authorization and to retire the Medical Benefit Policy (MBP) 46.0 Dacogen (decitabine) given the decreased cost, low volume and high approval percentage of Dacogen in recent years.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

ENHERTU

Background: Enhertu labeling has been updated to include the use of the PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody assay as an FDA approved companion diagnostic device for assessment of "HER2-low"status. The indication has been revised as below:

Enhertu for the treatment of adult patients with unresectable or metastatic HER2- low (IHC 1+ or IHC 2+/ISH-) breast cancer, as determined by an FDA-approved test, who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.

Recommendations: The following changes are recommended to Enhertu MBP 208.0:

Breast Cancer

- Prescription written by a hematologist or oncologist AND
- Medical record documentation of patient age greater than or equal to 18 years AND
- Medical record documentation of unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer, as detected by an FDA Approved test AND
- Medical record documentation that Enhertu will be used as a single agent AND
- Medical record documentation of one of the following:
    - Documentation of a prior chemotherapy in the metastatic setting OR
    - Documentation of disease recurrence during or within 6 months of completing adjuvant chemotherapy

Note: The FDA Approved tests for Enhertu are as follows:

Breast Cancer: PATHWAY anti-Her2/neu (4B5) Rabbit Monoclonal Primary Antibody (Ventana Medical Systems, Inc.)

Non-Small Cell Lung Cancer: Guardant360 CDx (Guardant Health, Inc.), Oncomine Dx Target Test (Life Technologies Corporation)

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

SITE OF CARE POLICY UPDATE

Background: On October 1st, 2019 Geisinger Health Plan (GHP) implemented a new site of care program for infliximab products and intravenous/subcutaneous immune globulin products, which direct members to the most cost-effective, yet clinically appropriate location to receive drug infusions under

the medical benefit. The site of care program is administered as part of the existing prior authorization program which requires clinical approval of the medication as well as approval at hospital based outpatient facilities via the following prior authorization criteria. Since that time, additional drugs have been added to the site of care program in phases.

On Feburary 15th, 2023 GHP will implement Phase 13 drugs (Ocrevus, Tysabri, Aveed, Givlaari and Oxlumo) to the site of care program. The current Site of Care Policy (MBP 181.0) will apply in addition to the drugs' respective existing clinical prior authorization program.

Recommendations: It is recommended that the following changes (highlighted in green) be made to MBP 181.0 so that this policy may apply to the Phase 13 drugs (Ocrevus, Tysabri, Aveed, Givlaari and Oxlumo). No changes are recommended to the criteria for self-injected drugs.

1. Abatacept (Orencia IV)	26. Immune Globulin (IVIG)
2. Agalsidase Beta (Fabrazyme)	27. Imiglucerase (Cerezyme)
3. Alglucosidase Alfa (Lumizyme)	28. Inebilizumab (Uplizna)
4. Alpha$_1$-Proteinase Inhibitor [Human] products	29. Infliximab & infliximab biosimilar products
5. Belimumab (Benlysta IV)	30. Laronidase (Aldurazyme)
6. Benralizumab (Fasenra)	31. Lumasiran (Oxlumo)
7. Burosumab (Crysvita)	32. Mepolizumab (Nucala)
8. C1 esterase Inhibitor [Human] (Cinryze)	33. Natalizumab (Tysabri)
9. Casimersen (Amondys 45)	34. Ocrelizumab (Ocrevus)
10. Canakinumab (Ilaris)	35. Omalizumab (Xolair)
11. Certolizumab (Cimzia)	36. Patisiran (Onpattro)
12. Crizanlizumab (Adakveo)	37. Ravulizumab (Ultomiris)
13. Denosumab (Prolia, Xgeva)	38. Romosozumab (Evenity)
14. Eculizumab (Soliris)	39. Sebelipase alfa (Kanuma)
15. Edaravone (Radicava)	40. Taliglucerase alfa (Elelyso)
16. Elapegademase-lvlr (Revcovi)	41. Teprotumumab (Tepezza)
17. Elosulfase alfa (Vimizim)	42. Testosterone udecanoate (Aveed)
18. Eptinezumab (Vyepti)	43. Tildrakizumab (Ilumya)
19. Eteplirsen (Exondys 51)	44. Tocilizumab (Actemra IV)
20. Evinacumab (Evkeeza)	45. Ustekinumab (Stelara)
21. Galsulfase (Naglazyme)	46. Vedolizumab (Entyvio)
22. Givosiran (Givlaari)	47. Velaglucerase alfa (Vpriv)
23. Golodirsen (Vyondys 53)	48. Vestronidase alfa-vjbk (Mepsevii)
24. Golimumab (Simponi Aria)	49. Viltolarsen (Viltepso)
25. Idursulfase (Elaprase)	50. Vutrisiran (Amvuttra)

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

SYNAGIS

Background: It is recommended to update the criteria for use and authorization duration of the Synagis policy MBP 2.0. The update to the Synagis policy is intended to capture parameters and processes during atypical respiratory syncytial virus (RSV) season.

Recommendations:

MBP 2.0 Synagis (palivizumab)
CRITERIA FOR USE:
The indication criteria is based on the American Academy of Pediatrics policy statement. Listed indications would need to be met on November 1 of the calendar year that prophylaxis is initiated. Members born after November 1 during RSV season who meet criteria will receive monthly prophylaxis until March 31st.
In the event of an atypical RSV season (ie. unpredicted, early or late, high rates of RSV circulation), listed indications may also be met on dates deemed appropriate by Geisinger Health Plan in conjunction with guidance from the American Academy of Pediatrics (AAP) and other applicable clinical resources.

AUTHORIZATION DURATION:
Prophylaxis of up to 5 doses should be initiated on November 1 (prior to RSV season) and continue until March 31. Listed indications would need to be met on November 1 of the calendar year that prophylaxis is initiated. Members born after November 1 during RSV season who meet criteria will receive monthly prophylaxis until March 31st.
In the event of an atypical RSV season (ie. unpredicted, early or late, high rates of RSV circulation), prophylaxis of up to 5 doses should be initiated and continued until the dates deemed appropriate by Geisinger Health Plan in conjunction with guidance from the American Academy of Pediatrics (AAP) and other applicable clinical resources. Members born after the start of the atypical RSV season who meet criteria will receive monthly prophylaxis until the date deemed appropriate by Geisinger Health Plan in conjunction with guidance from the American Academy of Pediatrics (AAP) and other applicable clinical resources.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

TURALIO (pexidartinib)

Background: Turalio is indicated for Tenosynovial giant cell tumor, and the current recommended dose is 400 mg twice daily (800 mg/day). On October 14, 2022, the introduction of 125 mg capsules and the removal of the 200 mg capsules was approved by the FDA. The new recommended dose is 250 mg orally twice daily with a low-fat meal (approximately 11 to 14 grams of total fat).

Current Tiering:
- Commercial – QL of 4 capsules per day, 30-day supply per fill
- Exchange – Tier 6 w/PA
- CHIP – Tier 2 w/PA
- Commercial 4th Tier – Tier 3 w/PA

Recommendations: (once 125 mg capsules become commercially available):
- No change to policies
- Add 125 mg capsules to same tier and with same QL as 200 mg capsules

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

XOLAIR (omalizumab)

Background: The current quantity limit listed in Commercial Policy 661.0 for Xolair does not allow members to receive a dose of 150 mg every 4 weeks for Chronic Idiopathic Urticaria, as is required before members can meet criteria for the 300 mg every 4 weeks dose. Currently, the quantity limit and overrides listed in the policy only incorporate the 300 mg every 4 weeks dosing under the chronic idiopathic urticaria section. One of the criteria points listed in the chronic idiopathic urticaria section is "Medical record documentation of a therapeutic failure on Xolair 150 mg dose, when Xolair 300 mg dose is requested." However, as stated above, the current policy override language does not allow for the 150 mg every 4 weeks dosing to be entered into the claims processing system.

Recommendations: It is recommended to update the quantity limit in Commercial Policy 661.0 for Xolair to allow for the Xolair 150 mg every 4 weeks dosing to be entered into authorizations, as follows.

QUANTITY LIMIT: *QLs must be entered within the authorization.*
- 150 mg every 4 weeks
    1. In PA Hub: Add PA, OQL, and max quantity dispensed 1.
        - QL FOR LETTER: 1 mL per 28 days
- 300 mg every 4 weeks
    1. In PA Hub: Add PA, OQL, and max quantity dispensed 2.
        - QL FOR LETTER: 2 mL per 28 days

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Voting responses were received from 33 of 51 members. The vote was unanimously approved.

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on January November 17th, 2023 at 1:00 p.m.

Meeting will be held virtually via phone/Microsoft Teams.