GHP P&T MINUTES

SEPTEMBER 20, 2016

P&T Committee Meeting Minutes
GHP Family Business
September 20, 2016

Present:	**Absent:**
Bret Yarczower, MD, MBA – Chair	Keith Boell, DO
Perry Meadows, MD	John Bulger, MD, Chief Medical Officer
Jamie Dodson, RPh	Dean Christian, MD
Kristen Bender, Pharm.D	William Seavey, Pharm.D.
Kristi Clarke, Pharm. D. – via phone	James Schuster, MD
Tricia Heitzman, Pharm.D.	Steve Tracy, Pharm.D.
Michelle Holt-Macey, Pharm.D. – via phone	Lori Zaleski, RPh
Lisa Mazonkey, RPh – via phone	Holly Bones, Pharm.D.
Thomas Morland, MD – via phone	Kimberly Clark, Pharm.D
Kristen Scheib, Pharm.D.	Phillip Krebs, R.EEG T.
Richard Silbert, MD – via phone	
Michael Spishock RPh – via phone	
Todd Sponenberg, Pharm.D., RPh	
Kevin Szczecina, RPh	
Elaine Tino, CRNP – via phone	
Keith Hunsicker Pharm.D.	
Beverly Blaisure, MD – via phone	
Michael Evans, Pharm.D., B.S – via phone	
John Flaherty, Pharm.D. – via phone	
Jonas Pearson, MS, RPh – via phone	

Call To Order:
Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, September 20, 2016.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the July 19, 2016 minutes as written. Todd Sponenberg made a motion to accept the minutes as written and Kevin Szczecina seconded the motion. None were opposed.

DRUG REVIEWS:

Impavido **Kristen Scheib**
(miltefosine)

Kristen cheib provided a review of Impavido to the committee for consideration as a pharmacy benefit. Impavido is indicated in adults and adolescents ≥12 years of age weighing ≥ 30 kg (66lbs) for the treatment of:

- Visceral leishmaniasis caused by Leishmania donovani
- Cutaneous leishmaniasis caused by Leishmania braziliensis, Leishmania guyanensis, and Leishmania panamensis
- Mucosal leishmaniasis caused by Leishmania braziliensis

Formulary alternatives:
Fluconazole, Ketoconazole, Itraconazole*
*Prior authorization required

Proposed Clinical Recommendations: Impavido is a pharmacy benefit and should not be added to the GHP Family formulary. A prior authorization with the following criteria should apply:

- Medical record documentation that the patient is at least 12 years of age **AND**
- Medical record documentation that the patient weighs at least 30 kg **AND**
- Prescription is written by a board certified infectious disease specialist **AND**
- Medical record documentation of one of the following:
    - Visceral leishmaniasis casued by L. donovani
    - Cutaneous leishmaniasis caused by L. braziliensis **OR** L. guyanensis **OR** L. panamensis
    - Mucosal leishmaniasis caused by L. braziliensis **AND**
- Medical record documentation of a negative pregnancy test for women of childbearing age **AND**
- Medical record documentation member has been counseled on use of contraception during therapy and for 5 months after **AND**
- Medical record documentation of no history of Sjögren-Larsson-Syndrome **AND**
- If diagnosis is visceral leishmaniasis, medical record documentation of therapeutic failure on, intolerance to or contraindication to Liposomal Amphotericin B

****A QL of a one-time fill for 84 capsules per 28 days and authorization duration of 1 month will apply**

Clinical Discussion: FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. For geriatric use, clinical studies of Impavido did not include sufficient numbers of subjects 65 years of age and over to determine if they respond differently than younger subjects.

Impavido is the first and only FDA-approved drug to treat cutaneous or mucosal leishmaniasis, in addition to visceral leishmaniasis. Liposomal amphotericin B is FDA-approved for treatment of visceral leishmaniasis. All other treatments would be considered off-label or are not commercially available in the

U.S. The FDA granted Impavido fast track designation, priority review, and orphan product designation. These designations were granted because the drug demonstrated the potential to fill an unmet medical need in a serious disease or condition, the potential to be a significant improvement in safety or effectiveness in the treatment of a serious disease or condition, and is intended to treat a rare disease, respectively.

Black Box Warning: Miltefosine may cause fetal harm. Fetal death and teratogenicity occurred in animals administered miltefosine at doses lower than the recommended human dose. Do not administer miltefosine to pregnant women. Obtain a serum or urine pregnancy test in females of reproductive potential prior to prescribing miltefosine. Advise females of reproductive potential to use effective contraception during therapy and for 5 months after therapy.

Clinical Outcome: Perry Meadows made a motion to accept the recommendations as amended. Todd Sponenberg seconded the motion. None were opposed.

Proposed Financial Recommendations: Impavido should not be added to the GHP Family formulary. No additional criteria should apply.

Financial Discussion: No questions or comments.

Financial Outcome: Kristen Bender made a motion to accept the recommendation as amended. Todd Sponenberg seconded the motion. None were opposed

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Approved Recommendations: Impavido will not be added to the GHP Family formulary. The following prior authorization criteria will apply:

- Medical record documentation that the patient is at least 12 years of age **AND**
- Medical record documentation that the patient weighs at least 30 kg **AND**
- Prescription is written by a board certified infectious disease specialist **AND**
- Medical record documentation of one of the following:
    - Visceral leishmaniasis casued by L. donovani
    - Cutaneous leishmaniasis caused by L. braziliensis **OR** L. guyanensis **OR** L. panamensis
    - Mucosal leishmaniasis caused by L. braziliensis **AND**
- Medical record documentation of a negative pregnancy test for women of childbearing age **AND**
- Medical record documentation member has been counseled on use of contraception during therapy and for 5 months after **AND**
- Medical record documentation of no history of Sjögren-Larsson-Syndrome **AND**
- If diagnosis is visceral leishmaniasis, medical record documentation of therapeutic failure on, intolerance to or contraindication to Liposomal Amphotericin B

****A QL of a one-time fill for 84 capsules per 28 days and authorization duration of 1 month will apply**

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

DEFITELIO **Kristi Clarke**
(defibrotide sodium)

Kristi Clarke provided a review of Defitelio to the committee for consideration as a medical benefit. Defitelio is indicated for the treatment of adult and pediatric patients with hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), with renal or pulmonary dysfunction following hematopoietic stem-cell transplantation.

Formulary alternatives: none

Proposed Clinical Recommendations: Because Defitelio would be administered during an inpatient stay, it is considered a medical benefit only. Although it will not require a prior authorization, based on clinical evidence, the following criteria is suggested for appropriate use and may be utilized for retrospective review. Defitelio should NOT be added to the GHP Family pharmacy formulary.

- Medical record documentation of a diagnosis of hepatic sinusoidal obstruction syndrome/ hepatic veno-occlusive disease as evident by at least one of the following:
    - 2 or more of the following events within 20 days of hematopoietic stem-cell transplantation:
        - Bilirubin ≥ 2 mg/dL OR
        - Hepatomegaly or right upper quadrant pain OR
        - Sudden weight gain due to fluid (>2% baseline body weight)

  OR
    - Bilirubin > 2 mg/dL within 21 days of hematopoietic stem-cell transplant AND 2 or more of the following
        - Hepatomegaly OR
        - Ascites OR
        - Weight gain > 5% from pre-transplant weight

  AND
- Medical record documentation of multi-organ dysfunction (pulmonary, renal, or both) AND
- Medical record documentation of an appropriate dose for the patient's weight*AND
- Medical record documentation of appropriate duration of therapy (no more than 60 days)

*****Appropriate dose for Defitelio is 6.25 mg/kg every 6 hours, based on patient's baseline weight. Baseline weight is defined as prior to the preparation regimen for hematopoietic stem-cell transplantation**.**

Clinical Discussion: FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. For geriatric use, clinical studies did not include enough patients greater than 65 years of age to determine their response to Defitelio when compared to younger patients.

Defitelio (defibrotide sodium) is indicated for the treatment of adult and pediatric patients with hepatic veno-occlusive disease, with renal or pulmonary dysfunction following hematopoietic stem-cell transplantation. Hepatic sinusoidal obstruction syndrome can be a very serious disease. It is characterized by hepatomegaly, pain, jaundice, and ascites. In severe cases, hepatic veno-occlusive leads to multi-organ dysfunction and mortality rates can be as high as 80%. Defitelio is administered as a 2-hour intravenous infusion at 6.25 mg/kg every 6 hours for 21 days to a maximum of 60 days, in an inpatient setting. Defitelio has been shown to improve the Day+ 100 survival rates and response rates in both children and adults in several trials. The most common adverse reactions were hypotension, diarrhea, vomiting,

nausea, and epistaxis. The most common serious adverse reactions were hypotension and pulmonary alveolar hemorrhage. Based on specialists' feedback, it seems defibrotide is reserved for patients with severe cases of SOS, however the FDA approval is for hepatic sinusoidal obstruction syndrome with renal or pulmonary dysfunction following hematopoietic stem-cell transplantation. The FDA indication does not define which classification of SOS (mild, moderate, severe) should receive treatment with Defitelio.

Defitelio is the only medication approved for hepatic veno-occlusive disease. Currently, the standard of care consists of supportive therapy. Although there have been advances in supportive care for transplant patients, the rate of mortality has not decreased.

Tricia Heitzman asked the committed how a retrospective review policy is maintained and operationalized at the heatlh plan. She stated that if it is located with the other medical/pharmacy policies, then it often causes confusion amongst providers, as they believe it requires authorization. A suggestion was made to have the guideline possibly reside with transplant policies. Perry Meadows suggested monitoring utilization and revisiting should utilization not be what is predicted/expected.

Clinical Outcome: Dr. Perry Meadows made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

Proposed Financial Recommendations: It is recommended that Defitelio not be added to the GHP Family formulary. The medication will not require prior authorization on the medical side.

Financial Discussion: No questions or comments.

Financial Outcome: Dr. Perry Meadows made a motion to accept the recommendation as written. Tricia Heitzman seconded the motion. None were opposed.

Approved Recommendations: Because Defitelio would be administered during an inpatient stay, it is considered a medical benefit. No prior authorization or retrospective review criteria will be developed at this time. Will monitor utilization for unexpected use. Defitelio should NOT be added to the GHP Family formulary.

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

XTAMPZA ER **Kristi Clarke**
(oxycodone)

Kristi Clarke provided a review of Xtampza ER to the committee for consideration as a pharmacy benefit. Xtampza ER is indicated for the management of severe pain that requires daily, around-the-clock, long-term opioid treatment and alternative treatment options are inadequate.

Limitations of use: The use of Xtampza ER should be reserved for use in patients whom alternative treatment options are ineffective, not tolerated, or would be inadequate to provide sufficient management of pain. Xtampza ER is not indicated as an as-needed analgesic.

Formulary alternatives: morphine sulfate ER^, fentanyl transdermal^, methadone^
^Quantity limits apply

Proposed Clinical Recommendations: It is recommended that Xtampza ER not be added to the GHP Family formulary. The following criteria will apply:

- Medical record documentation of a diagnosis of pain severe enough to require daily, around-the-clock, long-term opioid treatment **AND**
- Medical record documentation that the member is not currently taking any other long-acting opioids in combination with Xtampza ER **AND**
    - Medical record documentation of one of the following criteria:
    - Therapeutic failure on, intolerance to, or contraindication to three (3) long-acting formulary analgesic alternatives OR
    - Risk to abuse controlled substances by crushing

Quantity Limit: 2 capsules per day (exception: 36 mg capsules)

Clinical Discussion: FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. For Geriatric use, in controlled pharmacokinetic trials, patients older than 65 years had a slight reduction in clearance of oxycodone. When compared to young adults (age 21-45), the plasma concentration of oxycodone in the elderly was increased by 15%. In the Phase 3 study, 12% of patients were 65 years or older. No unexpected adverse reactions were seen in the elderly patients. Respiratory depression is the largest risk in elderly patients treated with opioids, titrate the dose of Xtampza ER slowly.

Xtampza ER is extended-release oxycodone with microsphere capsules formulated as an oxycodone base and inactive ingredients (fatty acids and waxes) that can deter from abuse. Xtampza was created with DETERx technology in order to prevent abuse by chewing, crushing, breaking, or dissolving. Therefore, it is able to maintain its pharmacokinetics even if it is chewed, lowering the risk of intentional/ unintentional abuse.

Black Box warning: Xtampza ER carries a warning around addition, abuse, and misuse, life threatening respiratory depression, accidental ingestion, neonatal opioid withdrawal syndrome, and cytochrome P450 3A4 interactions.

Clinical Outcome: Tricia Heitzman made a motion to accept the recommendations as written. Kristen Bender seconded the motion. None were opposed.

Proposed Financial Recommendations: Idelvion should not be added to the GHP Family formulary at this time. The following additional criterion should apply:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) long-acting formulary analgesic alternatives

Financial Discussion: No comments or questions.

Financial Outcome: Dr. Perry Meadows made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

Approved Recommendations: Xtampza ER will not be added to the GHP Family formulary at this time. The following prior authorization criteria will apply to requests for Xtampza ER:

- Medical record documentation of a diagnosis of pain severe enough to require daily, around-the-clock, long-term opioid treatment **AND**
- Medical record documentation that the member is not currently taking any other long-acting opioids in combination with Xtampza ER **AND**
    - Medical record documentation of one of the following criteria:
    o Therapeutic failure on, intolerance to, or contraindication to three (3) long-acting formulary analgesic alternatives OR
    o Risk to abuse controlled substances by crushing
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) long-acting formulary analgesic alternatives

Quantity Limit: 2 capsules per day (exception: 36 mg capsules)

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

CINAIR **Kristi Clarke**
(reslizumab)

Kristi Clarke provided a review of Cinqair to the committee for consideration as a pharmacy or medical benefit. Cinqair is indicated as add-on maintenance therapy for the treatment of severe asthma in patients 18 years and older with an eosinophilic phenotype.

-Studies producing positive outcomes observed patients with a blood eosinophil count of at least 400/mcL.

Formulary alternatives: none

Proposed Clinical Recommendations: Due to an expanded treatment age range, and better clinical outcomes associated with alternative medications, it is recommended that Cinqair, a medical benefit, not be placed on the Medicaid formulary at this time. Request for Cinqair should require a medical prior authorization with the following criteria:

- Documentation of patient age $\geq$ 18 years **AND**
- Patient must have severe persistent asthma **AND**
- Prescription written by an allergist or pulmonologist **AND**
- Medical record documentation of a blood eosinophil count of $\geq$ 400 cells/mcL since the time of asthma diagnosis **AND**
- Medical record documentation of:
    - Intolerance to or not well controlled or very poorly controlled symptoms* despite at least a 3 month trial of: high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
    - Two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist **AND**
- Insured individual must be adherent with current therapeutic regimen and must demonstrate appropriate inhaler technique **AND**
- Known environmental triggers within the member's control have been eliminated **AND**
- Medical record documentation that Cinqair is not being used in combination with Nucala or Xolair.

Clinical Discussion: FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed.

Cinqair is an Interleukin-5 Receptor Antagonist that may be used as an add-on maintenance treatment for severely asthmatic patients with an eosinophilic phenotype. It is given via IV infusion over 20-50 minutes. Some studies have shown positive results for treating a small subset of asthmatic patients. However, studies have shown Cinqair did not exhibit significant differences in exacerbations resulting in a hospitalization AND/OR emergency room visit when compared to placebo. Also, mixed results have been reported with regard to the medication's impact on the number of exacerbations experienced. Nucala, a medication with a similar indication as Cinqair, has shown a significant difference in the number of clinically significant exacerbations when compared to placebo.

Black Box warning: Anaphylaxis has been observed with reslizumab infusion in 0.3% of patients in placebo-controlled clinical studies. Anaphylaxis was reported as early as the second dose of reslizumab. Anaphylaxis can be life-threatening. Patients should be observed for an appropriate period of time after reslizumab administration by a health care professional prepared to manage anaphylaxis. Discontinue reslizumab immediately if the patient experiences signs or symptoms of anaphylaxis.

Clinical Outcome: Kevin Szczecina made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

Proposed Financial Recommendations: Cinqair will be a medical benefit. At this time it is recommended that it NOT be added to the formulary. Similar costs and decreased treatment age range, when compared to treatment alternatives, led to this recommendation. The following additional authorization criteria will apply:

- Therapeutic failure on, intolerance to, or contraindication to the use of Nucala

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 and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Financial Discussion: No comments or questions.

Financial Outcome: Dr. Perry Meadows mad a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

Approved Recommendations: Cinqair will not be added to the GHP Family formulary at this time and will be considered a medical benefit. The following prior authorization criteria will apply to requests for Cinqair:

- Documentation of patient age $\geq$ 18 years **AND**

- Patient must have severe persistent asthma **AND**
- Prescription written by an allergist or pulmonologist **AND**
- Medical record documentation of a blood eosinophil count of $\geq$ 400 cells/mcL since the time of asthma diagnosis **AND**
- Medical record documentation of:
    - Intolerance to or not well controlled or very poorly controlled symptoms* despite at least a 3 month trial of: high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
    - Two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist **AND**
- Insured individual must be adherent with current therapeutic regimen and must demonstrate appropriate inhaler technique **AND**
- Known environmental triggers within the member's control have been eliminated **AND**
- Medical record documentation that Cinqair is not being used in combination with Nucala or Xolair **AND**
- Therapeutic failure on, intolerance to, or contraindication to the use of Nucala

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 and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

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

TALTZ **Kristen Scheib**
(ixekizumab)

Kristen Scheib provided a review of Taltz to the committee for consideration as a pharmacy benefit.

Taltz is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are condidates for systemic therapy or phototherapy

Formulary alternatives: methotrexate, cyclosporine, azathioprine, Humira*, Enbrel*, Stelara* (*requires prior authorization)

Proposed Clinical Recommendations: Taltzshould not be added to the GHP Family formulary at this time. A prior authorization with the following criteria should apply:

- Prescription must be written by a dermatologist **AND**
- Member must be at least 18 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 involving crucial body areas such as the hands, feet, face, or genitals

Clinical Discussion: FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. For geriatric use, no dosage adjustments recommended.

Taltz is an IL-17A inhibitor used for the treatment of moderate-to-severe plaque psoriasis. Of the medications in the class of IL-17A inhibitors, it requires the fewest injections. Taltz has been shown in clinical trials to be superior in efficacy when compared to placebo and etanercept (Enbrel). Taltz is available in two forms, an auto-injector and a prefilled syringe. Both delivery devices can be self-administered when patients are educated on how to administer the medication correctly. It is dosed as two 80 mg injections at Week 0, followed by 80 mg at Weeks 2, 4, 6, 7, 10, and 12, and then 80 mg every 4 weeks thereafter.

Clinical Outcome: Kristen Bender made a motion to accept the recommendations as written. Dr. Perry Meadows seconded the motion. None were opposed.

Proposed Financial Recommendations: Taltz should not be added to the GHP Family formulary at this time. The following additional criterion should apply:

- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* AND Enbrel*

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 psoriasis on six (6) months of Taltz therapy is required.

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

QUANTITY LIMITS: Initial Authorization: Three (3) month auth for a maximum total quantity of 8mL; remainder of the 6 month auth duration, QL of 1ml per 28 days.

Reauthorization: QL of 1ml per 28 days

Financial Discussion: No questions or comments.

Financial Outcome: Dr. Perry Meadows made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

Approved Recommendations: Taltz should not be added to the GHP Family formulary. The following criteria should apply to requests for Taltz:

- Prescription must be written by a dermatologist **AND**
- Member must be at least 18 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 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 Enbrel*

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 psoriasis on six (6) months of Taltz therapy is required.

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

QUANTITY LIMITS: Initial Authorization: Three (3) month auth for a maximum total quantity of 8mL; remainder of the 6 month auth duration, QL of 1ml per 28 days.

Reauthorization: QL of 1ml per 28 days

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

ZEMBRACE SYMTOUCH **Kristen Scheib**
(sumatriptan succinate)

Kristen Scheib provided a review of Zembrace to the committee for consideration as a pharmacy benefit. Zembrace is indicated for the acute treatment of migraine with or without aura in adults who have been diagnosed with migraine.

Limitations of Use1: Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack reconsider the diagnosis before Zembrace SymTouch is administered to treat any subsequent attacks. Zembrace SymTouch injection is not indicated for the prevention of migraine attacks.

Formulary alternatives: sumatriptan (cartridge, tablet, vial, pen, syringe, spray), zolmitriptan, rizatriptan, naratriptan

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Proposed Clinical Recommendations: Zembrace SymTouch is a pharmacy benefit and should not be added to the GHP Family formulary. A prior authorization with the following criteria should apply:

- Medical record documentation of a diagnosis of migraines with or without aura **AND**
- Medical record documentation that patient is at least 18 years of age **AND**
- Medical record documentation the member is not using concurrent opioid or barbiturate therapy for migraine treatment

**Quantity Limit of 16 syringes (or 8 mL total) per 28 days.

Clinical Discussion: FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings,

Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. For geriatric use, clinical gtrials did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger patients. A cardiovascular evaluation is recommended for geriatric patients who have other cardiovascular risk factors (e.g., diabetes, hypertension, smoking, obesity, strong family history of CAD) prior to receiving Zembrace SymTouch injection.

Zembrace SymTouch (Sumatriptan Succinate) is available as a prefilled, ready-to-use, single dose, disposable auto-injector containing 3 mg sumatriptan. Zembrace SymTouch is a serotonin (5-HT) receptor agonist (triptan) indicated for acute treatment of migraine with or without aura in adults. It is not indicated for the prophylactic therapy of migraine. With the Sub-Q formulation, patients may experience relief faster (as early as 10 minutes in the one trial) than was seen with some higher doses. Higher doses may lead to quicker relief but may increase adverse effects. Zembrace may be a beneficial for members who experiencing nausea and vomiting or are unable to take oral medication. Based on the clinical trials, Zembrace does not appear to have a convincing clinical benefit compared to the other sumatriptan products.

Clinical Outcome: Dr. Perry Meadows made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

Proposed Financial Recommendations: It is recommended that Zembrace SymTouch not be added to the GHP Family formulary. The following additional criterion should apply:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to 3 different preferred alternative triptan products (one of which must be a generic sumatriptan injection).

Financial Discussion: No comments or questions.

Financial Outcome: Kevin Szczecina made a motion to accept the recommendations as written. Kristen Bender seconded the motion. None were opposed.

Approved Recommendations: Zembrace SymTouch will not be added to the GHP Family formulary. The following criteria will apply to requests for Zembrace SymTouch:

- Medical record documentation of a diagnosis of migraines with or without aura **AND**
- Medical record documentation that patient is at least 18 years of age **AND**
- Medical record documentation the member is not using concurrent opioid or barbiturate therapy for migraine treatment
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to 3 different preferred alternative triptan products (one of which must be a generic sumatriptan injection).

**Quantity Limit of 16 syringes (or 8 mL total) per 28 days.

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

FAST FACTS:

ENTOCORT **Kristi Clarke**
(budesonide enteric coated)

New Indication: Entocort is now indicated for the treatment of mild to moderate active Crohn's Disease (CD) involving the ileum and/or the ascending colon in patients 8 years of age and older who weigh more than 25 kilograms. Entocort EC is the first drug approved for use in children with active disease.

Previously indicated for use in adults only.

Clinical discussion: FDA Approved Indications, Clinical Evidence of Safety and Efficacy, Dosing Schedule, Warnings and Precautions, and Adverse Reactions were discussed.

Recommendation: Budesonide enteric coated capsules are generically available without a prior authorization therefore no formulary or policy updates are needed.

Discussion: No comments or questions.

Outcome: Kevin Szczecina made a motion to accept the recommendations as written. Kristen Scheib seconded the motion. None were opposed.

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

PROAIR RESPICLICK **Kristen Scheib**
(albuterol sulfate)

New Indication: Treatment or prevention of bronchospasm in children 4 to 11 years of age with reversible obstructive airway disease and for the prevention of exercise induced bronchospasm (EIB).

Clinical discussion: FDA Approved Indications, Clinical Evidence of Safety and Efficacy were discussed.

Recommendation: ProAir RespiClinck is currently non-formulary. No changes to Medicare formulary are recommended at this time.

Discussion: No comments or questions.

Outcome: Todd Sponenberg made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

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

BRILINTA **Lisa Mazonkey**
(ticagrelor)

A request was made that we review Brilinta and consider removing the prior authorization criteria that we currently have in place. The request for this review was based on information that ticagrelor was preferred to clopidogrel in post stent patients to prevent stent thrombosis.

Indication: Brilinta is indicated to reduce the rate of stent thrombosis in patients who have been stented for treatment of ACS or to reduce the rate of cardiovascular death, myocardial infarction (MI), and stroke in patients with acute coronary syndrome (ACS) or a history of MI.

Current prior authorization criteria: Non-formulary, PA required:
Medical record documentation of a diagnosis or ACS (unstable angina, non-ST elevation myocardial infarction (MI), or ST elevation MI) **OR** Medical record documentation of a history of myocardial infarction within the previous 3 years.

Clinical discussion: FDA Approved Indications, Clinical Evidence of Safety and Efficacy, recommendations from national agencies, data from antiplatelet adherence progam, and coverage determination requests were discussed.

In patients who had an acute coronary syndrome with or without ST-segment elevation, treatment with ticagrelor, as compared with clopidogrel, significantly reduced the rate of death from vascular causes, myocardial infarction, or stroke, without an increase in the rate of overall major bleeding but with an increase in the rate of non–procedure-related bleeding.

Despite the fact that the efficacy of clopidogrel is hampered by the slow and variable transformation of the prodrug to the active metabolite, modest and variable platelet inhibition, an increased risk of bleeding, and an increased risk of stent thrombosis and myocardial infarction in patients with a poor response. As compared with clopidogrel, prasugrel, another thienopyridine prodrug, has a more consistent and pronounced inhibitory effect on platelets, resulting in a lower risk of myocardial infarction and stent thrombosis, but is associated with a higher risk of major bleeding in patients with an acute coronary syndrome who are undergoing percutaneous coronary intervention (PCI).[2]

Recommendation: Based on the information presented, the current prior authorization criteria for ticagrelor for GHP Family will remain the same based on diagnosis only:
Medical record documentation of a diagnosis or ACS (unstable angina, non-ST elevation myocardial infarction (MI), or ST elevation MI) **OR** Medical record documentation of a history of myocardial infarction within the previous 3 years.

Discussion: No comments or questions.

Outcome: Kevin Szczecina made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

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

KEYTRUDA **Kristi Clarke**
(pembrolizumab)

Updated indication: Keytruda is now indicated for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum-containing chemotherapy.

Note: Per the FDA, this indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Updated Dosing Instructions[1]: HNSCC: 200 mg IV every 3 weeks administered over 30 minutes until disease progression, unacceptable toxicity, or for up to 24 months in patients without disease progression

Current Formulary Status:

- Medical benefit requiring PA or specialty tier on pharmacy formulary

Recommendation: It is recommended the following criteria is added to the Keytruda policy:

Head and Neck Squamous Cell Carcinoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of Head and Neck Squamous Cell Carcinoma that is recurrent or metastatic and had disease progression on or after platinum-containing chemotherapy

Discussion: No comments or questions.

Outcome: Trician Heitzman made a motion to accept the recommendations as written. Kristen Bender seconded the motion. None were opposed.

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

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CLASS REVIEW:

MULTIPLE SCLEROSIS CLASS REVIEW **Kristen Scheib**

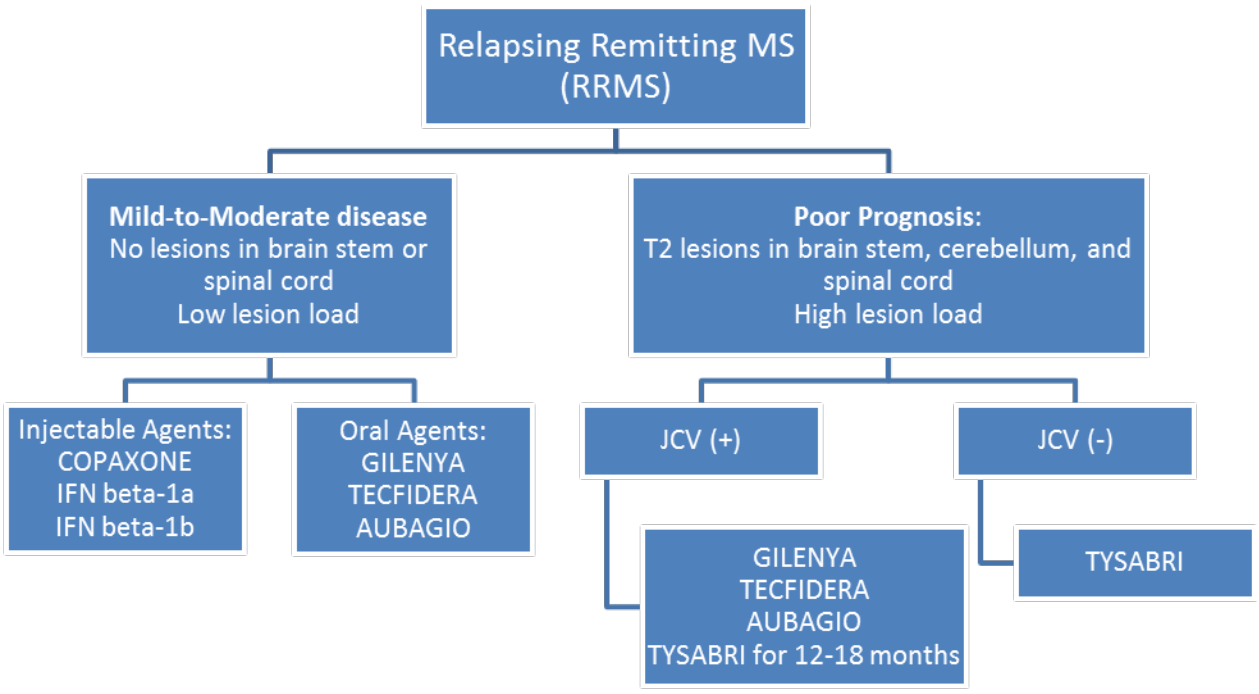
Kristen Scheib presented a class review of the agents used to treat Multiple Sclerosis to the committee. The review included the following agents

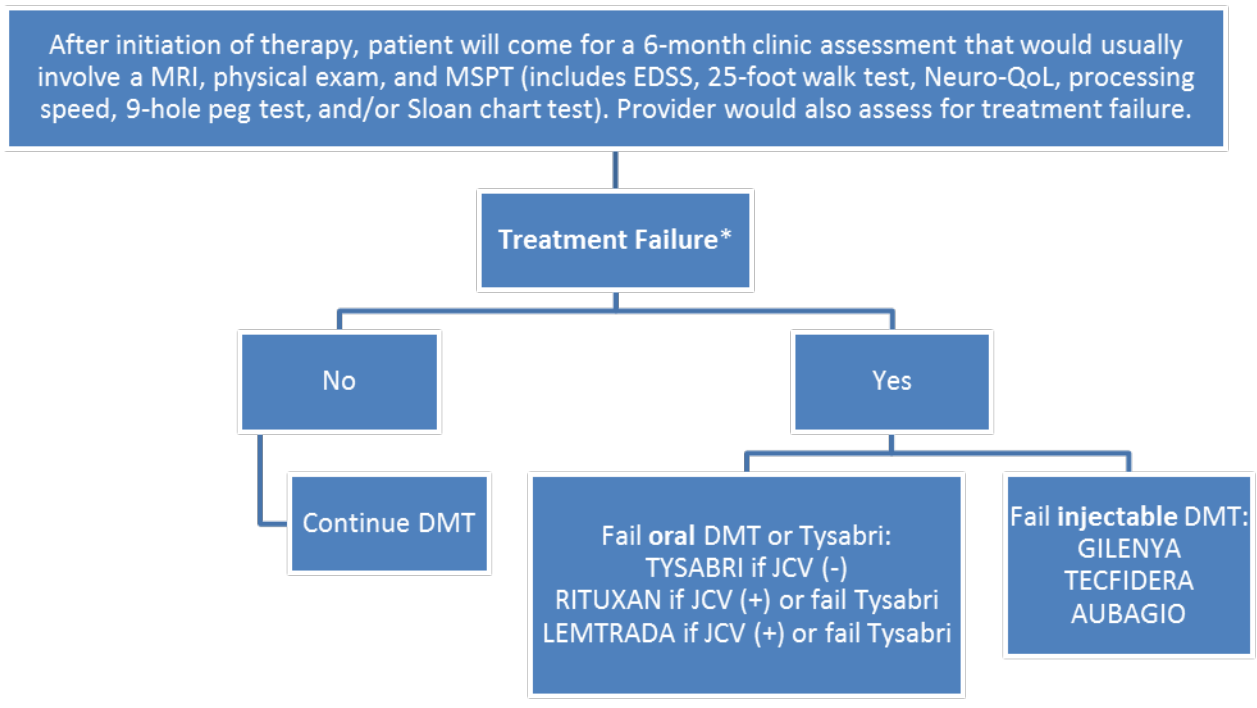
	How Supplied
Aubagio	7mg & 14mg tablets
Avonex	Kit: 30mcg/vial Prefilled Syringe: 30mcg/0.5ml
Betaseron	0.3mg kit for reconstitution
Copaxone	Prefilled syringe: 20mg/ml & 40mg/ml
Gilenya	0.5mg capsules
Extavia	0.3mg kit for reconstitution
Lemtrada	12mg/1.2ml IV solution
Plegridy	125mcg/0.5ml pen injector & prefilled syringe; starter pack
Rebif	Prefilled Syringe: 22mcg/0.5ml & 44mcg/0.5ml; titration pack Auto-injector: 22mcg/0.5ml & 44mcg/0.5ml; titration pack
Rituxan	100mg/10ml & 500mg/50ml IV solution
Tecfidera	120mg & 240mg delayed release capsules; starter pack
Tysabri	300mg/15ml IV concentrate
Zinbryta	150mg/ml prefilled syringe

Current formulary medications: Avonex*, Betaseron, Copaxone, Gilenya, Rebif*, Tecfidera (*requires prior authorization

Specialist Feedback:

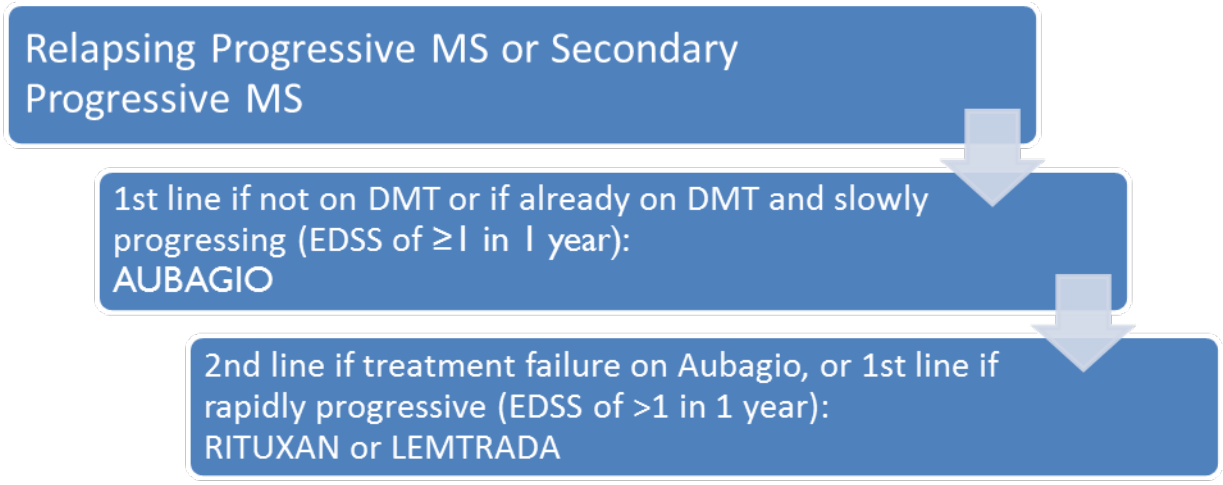
Appendix 1: GHS Treatment Algorithm for Relapsing Remitting Multiple Sclerosis (RRMS)



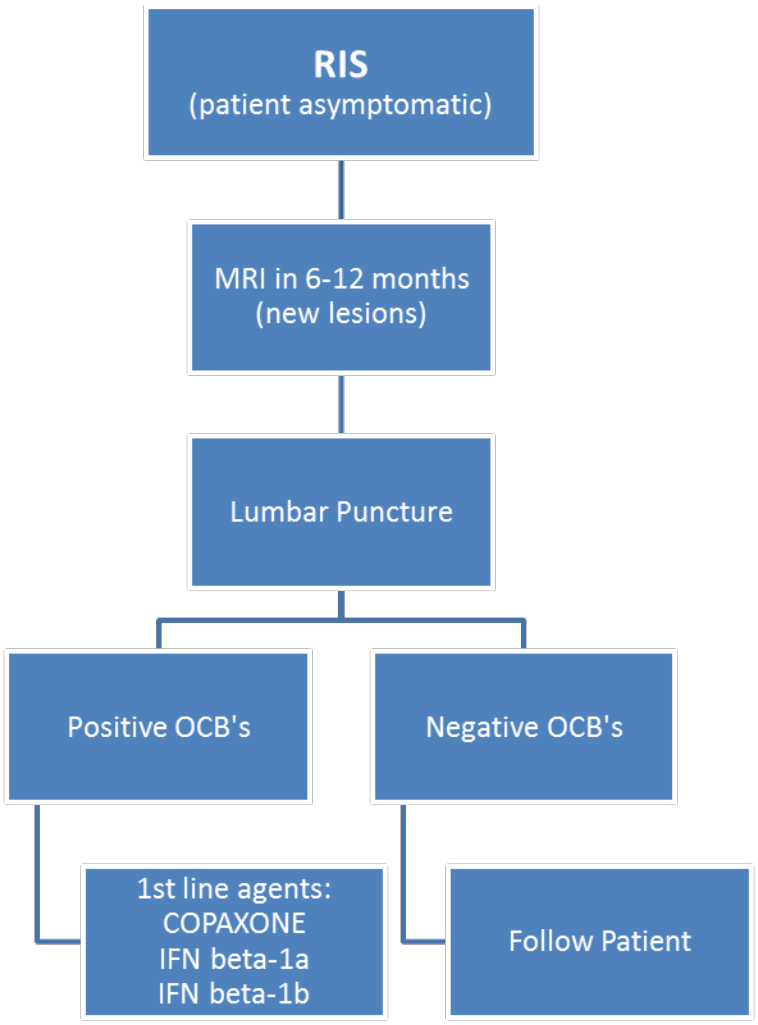


*Treatment failure is definded as having adverse effects to DMT, experiencing progression of the disease, relapsing in the first year (not in the first 3 months), or getting ≥ 2 new MRI lesions (T/2 gadolinium-enhansing) without relapses.

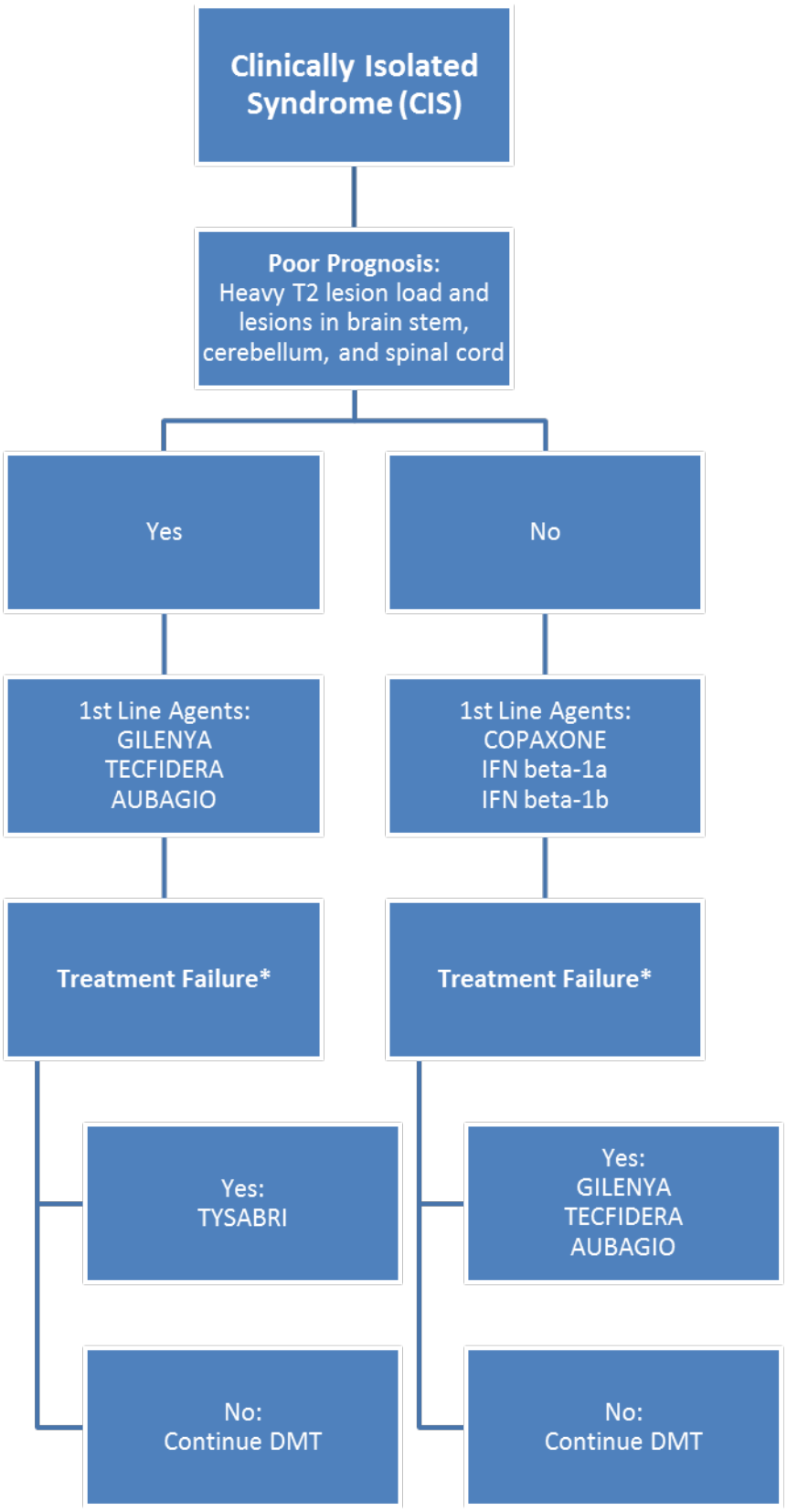
Appendix 2: GHS Treatment Algorithm for Progressing Multiple Sclerosis (PMS)



Appendix 3: GHS Treatment Algorithm for Radiologically Isolated Syndrome (RIS)



Appendix 4: GHS Treatment Algorithim for Clinically Isolated Syndrome (CIS)



*Treatment failure is definded as having adverse effects to DMT, experiencing progression of the disease, relapsing in the first year (not in the first 3 months), or getting ≥ 2 new MRI lesions (T/2 gadolinium-enhansing) without relapses.

Proposed Clinical and Financial Recommendations:

GHP FAMILY – EFFECTIVE 1/1/2017	
Aubagio	Aubagio is a pharmacy benefit and should be added to the GHP Family formulary at the Brand Tier **Prior authorization will be required for 7mg ONLY, with the following criteria:** - Medical record documentation as to why patient is unable to take 14mg tablet once daily ***QL: 1 tablet per day***
Avonex	Avonex is a pharmacy benefit and should remain on the GHP Family formulary at the Brand Tier. No prior authorization should apply at this time. ***QL: 2ml (4 syringes)/28 days***
Betaseron	Betaseron is a pharmacy benefit and should remain on the GHP Family formulary at the Brand Tier. No prior authorization should apply at this time. ***QL: 14 kits/28 days***
Copaxone	Copaxone is a pharmacy benefit and should remain on the GHP Family formulary at the Brand Tier. No prior authorization should apply at this time. ***QL: 20mg syringe – 1ml (1 syringe)/day*** ***QL: 40mg syringe – 12ml (12 syringes)/28 days***
Gilenya	Gilenya is a pharmacy benefit and should remain on the GHP Family formulary at the Brand Tier. No prior authorization should apply at this time. ***QL: 1 capsule/day***
Extavia	Extavia is a pharmacy benefit and should be added to the GHP Family formulary at the Brand Tier. No prior authorization should apply at this time. ***QL: 14 kits or vials/28 days***
Lemtrada	Lemtrada is a medical benefit and should not be added to the GHP Family formulary. **The following prior authorization criteria should apply:** - Medical record documentation of diagnosis of relapsing form of multiple sclerosis AND - Medical record documentation of age 17 or older AND - Medical record documentation that patient is using Lemtrada as monotherapy AND - Medical record documentation that Lemtrada is prescribed by a neurologist AND - Medical record documentation that patient is receiving pre-medication w/ high dose corticosteroids and herpetic prophylaxis during therapy AND - No medical record documentation of active/chronic infection AND - Medical record documentation that patient is NOT receiving therapy with concomitant antineoplastic, immuosuppressive, or immune modulating therapies AND - Medical record documentation the patient has not received any vaccines in the past 6 weeks and no plan to give any live vaccines while on therapy AND - Medical record documentation that patient is up to date on all required vaccinations AND - Documentation of positive antibody for varicella zoster (either physician documented diagnosis or vaccination history) AND

	- Medical record documentation of therapeutic failure on, contraindication to, or intolerance to three formulary alternatives, one of which must be Tysabri. **Auth Duration:** 1 year initial authorization, 1 month reauthorization **Reauth Criteria:** - Medical record documentation that Lemtrada is being used as monotherapy AND - Medical record documentation that patient has not started therapy with another DMT since initial 5 doses AND - Medical record documentation that remaining 3 doses are being administered 1 year after initial 5 doses AND - Medical record documentation that patient is receiving pre-medication w/ high dose corticosteroids and herpetic prophylaxis during therapy AND - No medical record documentation of active/chronic infection AND - Medical record documentation that patient is NOT receiving therapy with concomitant antineoplastic, immuosuppressive, or immune modulating therapies AND - Medical record documentation the patient has not received any vaccines in the past 6 weeks and no plan to give any live vaccines while on therapy AND - Medical record documentation that patient is up to date on all required vaccinations ***QL: 5 doses (60mg) for initial authorization, 3 doses (36mg) for reauthorization, total lifetime max of 8 doses***
Plegridy	Plegridy is a pharmacy benefit and should be added to the GHP Family formulary at the Brand Tier. No prior authorization should apply at this time. ***QL: 1ml (2 syringes)/28 days***
Rebif	Rebif is a pharmacy benefit and should remain on the GHP Family formulary at the Brand Tier. No prior authorization should apply at this time. ***QL: 6ml (12 syringes)/28 days***
Rituxan	Rituxan is a medical benefit and should not be added to the GHP Family formulary at this time. **The following prior authorization criteria should apply:** <u>Primary Progressive MS (PPMS)</u> 1. Medical record documentation of prescription written by a neurologist AND 2. Medical record documentation of a diagnosis of PPMS <u>Secondary Progressive MS (SPMS)/Relapsing Progressive MS</u> 1. Medical record documentation of prescription written by a neurologist AND 2. Medical record documentation of a diagnosis of SPMS or relapsing progressive MS AND 3. Medical record documentation of rapidly progressing disease (ex. EDSS score increase of >1 in 1 year) OR 4. Medical record documentation of slowly progressing disease (ex. EDSS score change of <u>≤</u> 1 in 1 year) and therapeutic failure on, contraindication to, or intolerance to Aubagio ^

	Relapsing/Remitting MS (RRMS) 1. Medical record documentation of prescription written by a neurologist AND 2. Medical record documentation of a diagnosis of RRMS AND 3. Medical record documentation of therapeutic failure on, contraindication to, or intolerance to three alternatives one of which must be Tysabri* OR 4. Medical record documentation of poor prognosis and therapeutic failure on, contraindication to, or intolerance to Tysabri* *NOTE: According to the American Academy of Neurology recommendation, Tysabri may be considered as a first line therapy in individuals with relapsing remitting multiple sclerosis who exhibit particularly aggressive initial course of disease and in whom the potential benefit is felt to outweigh the risk. Patients with a poor prognosis/aggressive disease include those with a heavy T2 lesion load, lesions in brain stem, cerebellum, and spinal cord.* (* requires prior authorization, ^QL apply) (**NOTE to reviewer: Studied dose is 1gm given on day 1 and 15, repeated every 6 months**) ***Auth duration: 6 months***
Tecfidera	Tecfidera is a pharmacy benefit and should remain on the GHP Family formulary at the Brand Tier. No prior authorization should apply at this time. ***QL: 2 caps/day***
Tysabri	Tysabri is a medical benefit and should not be added to the GHP Family formulary at this time. **The following prior authorization should apply:** - Medical record documentation of a diagnosis of relapsing/remitting multiple sclerosis **AND** - Medical record documentation that the patient 18 years or older **AND** - Medical record documentation that Tysabri is being prescribed by a neurologist **AND** - Patient is enrolled in a risk-minimization program, called the TOUCH™ Prescribing Program, **AND** - Physician documentation that Tysabri is being used as monotherapy is provided. **AND** - Medical record documentation that the member has been tested for anti-JCV antibody prior to start of Tysabri therapy. o If patient is anti-JCV antibody positive, medical record documentation that benefits of drug outweigh the risks of progressive multifocal leukoencephalopathy (PML) and patient is aware of increased PML risk **AND** - Medical record documentation of therapeutic failure on, contraindication to, or intolerance to two formulary alternatives. *NOTE: According to the American Academy of Neurology recommendation, Tysabri may be considered as a first line therapy in individuals with relapsing remitting multiple sclerosis who exhibit particularly aggressive initial course of disease and in whom the potential benefit is felt to outweigh the risk. Patients with a poor prognosis/aggressive disease include those with a heavy T2 lesion load, lesions in brain stem, cerebellum, and spinal cord.* **Auth Duration:** 1 year

	For re-authorization, medical record documentation of patient adherence to medication and improvement in signs and symptoms of multiple sclerosis while on Tysabri therapy will be required. • For patients who were previously anti-JCV antibody negative, medical record documentation that physician has re-tested for anti-JCV antibody status within the last 12 months. • For patients who were anti-JCV antibody positive at baseline or on re-test, medical record documentation that benefits of continuing drug outweigh risks.
Zinbryta	Zinbryta is a pharmacy benefit and should not be added to the GHP Family formulary at this time. **The following prior authorization criteria should apply:** - Prescription written by neurologist AND - Diagnosis of relapsing form of multiple sclerosis AND - Medical record documentation of age 18 years or older AND - Medical record documentation of therapeutic failure on, contraindication to, or intolerance to three formulary alternatives. ***QL: 1ml (1 syringe)/28 days***

Clinical Discussion: Disease state background, treatment guidelines, and specialist feedback were discussed. No comments or questions. It is the intention to allow greater access to these agents to allow to treat with the most appropriate patient based therapy. Earlier, more aggressive treatment during the inflammatory stages of the disease will hopefully correlate with better long term outcomes.

Clinical Outcome: Jamie Dodson made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

Financial Discussion: No comments or questions.

Financial Outcome: Kevin Szczecina made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

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

POLICY UPDATES:

HIV QUANTITY LIMITS — Kevin Szczecina

Quantity limit changes are proposed for the following HIV medications based on maximum recommended dosing information:

Brand Name	Generic Name	Dosage	QL to be added
NRTIs			
Zerit 1 mg/mL solution^ (200 mL bottle)	stavudine	Max – 40 mg (40 mL) every 12 hours	2400 mL/30 days
NNRTIs			
Rescriptor 100 mg tablet	delavirdine	400 mg TID	360/30 days
Intelence 25 mg tablet	etravirine	Based on weight	120/30 days
Intelence 100 mg tablet	etravirine	Based on weight	60/30 days

Discussion: No comments or questions.

Outcome: Kristen Bender made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

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

POLICY 143 UPDATES (P&T POLICY) — Jamie Dodson

Policy 143 revisions were proposed to the committed for review/approval. Summary of changes are as follows:

- Chief Medical officer no longer has to be a permanent member of the P&T committee, but will remain responsible for selecting the chairperson of the committee
- Beginning in 2017, conflict of interest attestations will no longer be required prior to every meeting, and will only be required yearly. It will be the responsibility of the voting member to notify the committee of any such disclosures

REXULTI POLICY UPDATE — Kevin Szczecina

Recommendation: Prior to July 2016 aripiprazole required prior authorization and as a result authorization for Rexulti only required failure on a four week trial of combination therapy of aripiprazole and an antidepressant for major depressive disorder and failure on aripiprazole for schizophrenia. Since aripiprazole was added to the GHP Family formulary without restriction it is recommended the criteria be changed to:

For MDD:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least a 4 week trial of combination therapy with aripiprazole and an antidepressant **AND**

- One of the following:
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least a 4 week trial of combination antidepressant therapy (such as an SSRI and bupropion or an SNRI and bupropion) OR
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least a 4 week trial of an antidepressant with augmentation therapy (including, but not limited to lithium, valproate, carbamazepine and lamotrigine)

For schizophrenia:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three generic, formulary atypical antipsychotics

Discussion – no questions or comments

Outcome: Tricia Heitzman made a motion to accept the recommendations as written. Kristen Scheib seconded the motion. None were opposed.

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

QUARTERLY CASE AUDITS — Todd Sponenberg

A quarterly case audit meeting was held on September 1, 2016. No formulary changes recommended

Meeting adjourned at 4:28 pm.

Future Scheduled Meetings

September 20, 2016 at 1:00 HCN3A & 3B Conference room

All of these meetings are scheduled to be held at Geisinger Health Plan, Hughes Center North and South Buildings; 108 Woodbine Lane; Danville, PA 17821.