**P&T Committee Meeting Minutes**
**Medicaid**
**May 16, 2023**

| **Present (via Teams):** | **Absent:** |
|---|---|
| Bret Yarczower, MD, MBA – Chair | Kristen Bender, Pharm.D. |
| Amir Antonius, Pharm.D. | Jeremy Bennett, MD |
| Emily Antosh, Pharm.D. | Holly Bones, Pharm.D. |
| Kim Castelnovo, RPh | Alyssa Cilia, RPh |
| Kimberly Clark, Pharm.D. | Michael Evans, RPh |
| Bhargavi Degapudi, MD | Jason Howay, Pharm.D. |
| Michael Dubartell, MD | Derek Hunt, Pharm.D. |
| Rajneel Farley, Pharm.D. | Kerry Ann Kilkenny, MD |
| Kelly Faust Pharm.D. | Briana LeBeau, Pharm.D. |
| Tricia Heitzman, Pharm.D. | Tyreese McCrea, Pharm.D. |
| Nichole Hossler, MD | Jonas Pearson, RPh |
| Emily Hughes, Pharm.D. | William Seavey, Pharm.D. |
| Keith Hunsicker, Pharm.D. | Michael Shepherd, MD |
| Kelli Hunsicker, Pharm.D. | |
| Philip Krebs, R.EEG T | |
| Ted Marines, Pharm.D. | |
| Lisa Mazonkey, RPh | |
| Perry Meadows, MD | |
| Jamie Miller, RPh | |
| Mark Mowery, Pharm.D. | |
| Austin Paisley, Pharm.D. | |
| Kimberly Reichard, Pharm.D. | |
| Melissa Sartori, Pharm.D. | |
| Angela Scarantino | |
| Kristen Scheib, Pharm.D. | |
| Leslie Shumlas, Pharm.D. | |
| Aubrielle Smith Pharm.D. | |
| Kirsten Smith, Pharm.D. | |
| Michael Spishock, RPh | |
| Todd Sponenberg, Pharm.D. | |
| Jill Stone, Pharm.D. | |
| Robert Strony, MD, MBA | |
| Luke Sullivan, DO | |
| Kevin Szczecina, RPh | |
| Amanda Taylor, MD | |
| Ariana Wendoloski, Pharm.D. | |
| Brandon Whiteash, Pharm.D. | |
| Margaret Whiteash, Pharm.D. | |
| Jeremy Garris, Pharm.D. (non-voting participant) | |
| Marianne Linko (non-voting participant) | |
| Dionardo Medina Encarnacion, MD (non-voting participant) | |
| Sarah Tucker (Pharmacy Resident) | |

**Call to Order:** Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, May 16, 2023.

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**Review and Approval of Minutes, Reviews, Fast Facts, and Updates:** Dr. Bret Yarczower asked for a motion or approval to accept the March 21, 2023 minutes as written. Minutes approved unanimously. None were opposed.

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**DRUG REVIEWS**

**Hemgenix (etranacogene dezaparvovec-drlb)**

**Review:** Hemgenix is an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with hemophilia B (congenital Factor IX deficiency) who: currently use Factor IX prophylaxis therapy, or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes. People with hemophilia A have a deficiency in factor VIII and patients with hemophilia B have a deficiency in Factor IX.

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion**: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Hemgenix will be a medical benefit and should not be added to the formulary. Hemgenix will require a prior authorization with the following criteria.

- Prescription written by or in consultation with a hematologist AND
- Medical record documentation that the member is a male based on assigned sex at birth and age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of moderate or severe hemophilia B with Factor IX level < 2 IU/dL or ≤ 2% of normal AND
- Medical record documentation of one of the following:
    - Member has current use of Factor IX prophylaxis therapy for at least 2 months with > 150 exposure days^ of treatment with Factor IX protein
    - Member has current of historical life-threatening hemorrhage
    - Member has repeated, serious spontaneous bleeding episodes

AND

- Medical record documentation that the member has a recent negative inhibitor status to Factor IX prior to administration of Hemgenix AND
- Medical record documentation that the member does not have an active hepatitis B or hepatitis C infection* assessed within the last 6 months AND
- Medical record documentation that the member does not have uncontrolled HIV** assessed within the last 6 months AND
- Medical record documentation that the member does not have evidence of advanced cirrhosis*** assessed within the last 6 months AND
- Medical record documentation that the member has not received any previous gene therapy for hemophilia B AND
- Medical record documentation that Hemgenix is being dosed according to the Food and Drug Administration approved labeling**** AND
- Medical record documentation of the frequency of bleeds within the previous 12 months AND
- Medical record documentation of therapeutic failure on Factor IX prophylaxis therapy

^Exposure days is the number of days a patient was exposed to exogenous factor.
*In the Hope-B trial members were excluded at screening if they were currently receiving antiviral therapy for this/these infection(s) and/or positive for any of the following: Hepatitis B surface antigen, except if in the opinion of the investigator this is due to a previous Hepatitis B vaccination rather than an active Hepatitis B infection, Hepatitis B virus deoxyribonucleic acid (HBV DNA), Hepatitis C virus ribonucleic acid (HCV RNA)
**In the Hope-B trial members were excluded at screening and the last lead-in visit if they had a positive human immunodeficiency virus (HIV) serological test, not controlled with anti-viral therapy as shown by CD4+ counts ≤200/microL
***In the Hope-B trial members were excluded at screening and the last lead-in visit if they had ALT > 2 times upper limit of normal (ULN), AST > 2 times ULN, total bilirubin > 2 times ULN, alkaline phosphatase (ALP) > 2 times ULN, creatinine > 2 times ULN. Also patients were excluded at screening if they had any known significant medical condition that may significantly impact the transduction of the vector and/or expression and activity of the protein, including but not limited to: disseminated intravascular coagulation, accelerated fibrinolysis, advanced liver fibrosis (suggestive of or equal to METAVIR Stage 3 disease; e.g., a FibroScan™ score of ≥9 kPa is considered equivalent)
****Hemgenix is administered as a single IV infusion. To calculate the Hemgenix dose use the following equation:

Hemgenix dose (in mL)= patient body weight (in kilogram) X 2

Number of vials needed= Hemgenix dose (in mL) / 10 (round up to the next whole number of vials)

**Note to Reviewer:** In the HOPE-B study, patients were assessed for AAV5 neutralizing antibodies using a clinical laboratory test, but patients were not excluded based on their test results nor are they excluded in our approved indication. The subject sub-group with detectable preexisting neutralizing anti-AAV5 antibodies up to titers of 1:678 showed mean Factor IX activity that was numerically lower compared to that subject sub-group without detectable preexisting neutralizing anti-AAV5 antibodies. In one subject with a preexisting neutralizing anti-AAV5 antibody titer of 1:3212, no human Factor IX expression was observed. Patients who intend to receive treatment with Hemgenix are encouraged to enroll in a study to measure pre-existing anti-AAV5 neutralizing antibodies by calling CSL Behring at 1-800-504-5434. Although there is no FDA-approved AAV5 NAb assay, CSL will make available a laboratory developed, CLIA-validated test that was used during the clinical trial. If a provider is interested in ordering this kit, free of charge, they can call 1-833-436-0021, Mon–Fri, 8 AM–8 PM ET (https://labeling.cslbehring.com/PRODUCT-DOCUMENT/US/Hemgenix/HEMGENIX-Patient-Eligibility-Brochure.pdf).

**Authorization Duration:** One (1) time approval per lifetime; Requests for authorizations exceeding these limits will require the following 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 beyond the FDA-approved treatment duration.

**Require RPH Sign off:** Yes

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

**Lunsumio (mosunetuzumab-axgb)**

**Review:** Lunsumio is a bispecific CD20-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy. This indicated is an accelerated approval based on response rate. Lunsumio binds the CD3 receptor expressed on the surface of T-cells and CD-20 expressed on the surface of lymphoma cells and some healthy B-lineage cells. In-vitro, the activated T-cells caused the release of pro-inflammatory cytokines and induced lysis of B-cells. NCCN recommends Lunsumio as a third-line or later treatment for follicular lymphoma (Category 2A).

**Clinical Discussion:** The committee unanimously voted to accept the recommendations.

**Financial Discussion**: The committee unanimously voted to accept the recommendations.

**Outcome:** Lunsumio is a medical benefit that will be managed by GHP and will require a prior authorization. The following prior authorization criteria should apply:

- Medical record documentation that Lunsumio is written by a hematologist or oncologist AND
- Medical record documentation of age greater than or equal to 18 years of age AND
- Medical record documentation of a diagnosis with relapsed or refractory follicular lymphoma AND
- Medical record documentation of prior treatment with two or more lines of therapy

**GPI Level:** GPI-12

**Authorization Duration:** Approval of Lunsumio will be given for an initial authorization of 6 months or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be given for 12 months or less if the reviewing provider feels it is medically appropriate, not to exceed the limitations outlined below.

Authorization of Lunsumio for the treatment of relapsed or refractory follicular lymphoma should not exceed the FDA-approved treatment duration of 8 total cycles for patients who are in complete remission following 8 cycles of Lunsumio treatment.

Authorization of Lunsumio for the treatment of relapsed or refractory follicular lymphoma should not exceed the FDA-approved treatment duration of 17 total cycles for patients who are in partial remission or stable disease following 8 cycles of Lunsumio treatment.

For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

**Formulary Alternatives:** Aliqopa

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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**Aduhelm (aducanumab - avwa)**

**Review:** Aduhelm is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's Disease (AD). Treatment should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease (the population studied in clinical trials). There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. The indication was approved under accelerated approval based on the reduction in amyloid beta plaques observed, and continued approval may be based upon confirmation of clinical benefit in confirmatory trials. The recommended dose of Aduhelm is 10 mg/kg to be given after initial titration. Initial titration is 1mg/kg on infusions one and two, 3 mg/kg on infusions three and four, 6 mg/kg on infusions five and six, and 10mg/kg on infusion seven and beyond. All titration and maintenance doses should be administered as an intravenous (IV) infusion given over approximately one hour, every 4 weeks (at least 21 days apart). Aduhelm is supplied in either one of two cartons. One carton (NDC 64406-101-01) contains one single-dose vial at a strength of 170mg/1.7mL (red cap). Another carton (NDC 64406-102-02) contains one single-dose vial at a strength of 300mg/3mL (blue cap). Aduhelm is the first drug for AD approved in over 18 years, the first drug approved to slow the progression of AD, and the first anti-amyloid monoclonal antibody approved for the treatment of AD.

**Clinical Discussion:** The committee unanimously voted to accept the recommendations.

**Financial Discussion**: Given that the clinical benefit of Aduhelm isn't well supported, is Leqembi better clinically and can we consider preferring the other product based on efficacy? As of right now they're both approved through accelerated approval, but in general most people would likely agree that Leqembi has better efficacy results compared to Aduhelm. If Leqembi is fully approved in the future, it will be likely that Leqembi will be clinically superior to Aduhelm. Because the outcomes of current clinical trials measured for both products were the same, we don't have the data to support at this point. Additional approval for Leqembi is anticipated in the next two months and policy changes may be necessary. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Aduhelm is a medical benefit managed by GHP and will require prior authorization. The following prior authorization will apply:

- Medical record documentation Aduhelm (aducanumab-avwa) is prescribed by or in consultation with a dementia specialist (e.g. neurologist, psychiatrist, geriatric psychiatrist, neuropsychiatrist, geriatrician, or gerontologist) **AND**
- Medical record documentation that the dementia specialist will monitor the beneficiary at least once every 3 months **AND**
- Medical record documentation of a diagnosis of Mild Cognitive Impairment (MCI) due to Alzheimer's Disease (AD) or mild dementia due to Alzheimer's Disease (AD) [diagnosis codes may include: G30, G30.0, G30.1, G30.8, G30.9, G31.84] **AND**
- Medical record documentation of no medical or neurological conditions (other than Alzheimer's disease) that might be a significant contributing cause of the beneficiary's cognitive impairment **AND**
- Medical record documentation of no contraindications to Magnetic Resonance Imaging (MRI) (e.g. cardiac pacemaker/defibrillator or ferromagnetic metal implants) **AND**
- Medical record documentation of MRI obtained within one year prior to initiating treatment with Aduhelm (aducanumab-avwa) **AND**
- Medical record documentation of positron emission tomography (PET) scan positive for brain amyloid plaques OR cerebrospinal fluid (CSF) biomarker testing positive for beta-amyloid plaques (as indicated by reduced amyloid beta 42 [Aβ42] levels OR reduced amyloid beta 42 amyloid beta 40 ratio [Aβ42/Aβ40 ratio] in CSF) **AND**
- Medical record documentation of at least two (2) of the following:
    - Mini-Mental State Examination (MMSE) score of greater than or equal to 24,

    - Montreal Cognitive Assessment (MoCA) score greater than or equal to 18,
    - Clinical Dementia Rating-Global Score (CDR-GS) of 0.5,
    - Clinical Dementia Rating-Sum of Boxes (CDR-SB) score less than or equal to 9,
    - Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) score less than or equal to 85, and/or
    - Quick Dementia Rating System (QDRS) score less than or equal to 12 **AND**
- Medical record documentation that member does not have any exclusions to treatment with Aduhelm (aducanumab-avwa), including all of the following:
    - A history of stroke, transient ischemic attack (TIA), or unexplained loss of consciousness in the past year AND
    - Poorly controlled diabetes mellitus AND
    - A brain MRI showing evidence of acute or sub-acute micro- or macro-hemorrhage, greater than 4 microhemorrhages, cortical infarct, or greater than 1 lacunar infarct AND
    - Current use of anticoagulants (except for aspirin at a prophylactic dose or less) **AND**
- Medical record documentation of a dose that is consistent with FDA-approved package labeling.

**GPI Level:** GPI-12

**Authorization Duration & Reauthorization Criteria:** Approval will be given for an initial duration of **twelve (12) months** or less if the reviewing provider feels it is medically appropriate. After the initial twelve (12) month approval, subsequent approvals will be for a duration of **twelve (12) months** or less if the reviewing provider feels it is medically appropriate, and will require:

- Medical record documentation that member continues to experience medical benefit from and tolerability to Aduhelm (aducanumab-avwa) based on the prescriber's assessment **AND**
- Medical record documentation Aduhelm (aducanumab-avwa) is prescribed by a dementia specialist (e.g., neurologist, psychiatrist, geriatrician, or geriatric psychiatrist) **AND**
- Medical record documentation that the member was, and will continue to be, monitored and assessed by the prescribing dementia specialist at least every 3 months **AND**
- Medical record documentation of no medical or neurological conditions (other than Alzheimer's disease) that might be a significant contributing cause of the beneficiary's cognitive impairment **AND**
- Medical record documentation of no contraindications to Magnetic Resonance Imaging (MRI) (e.g. cardiac pacemaker/defibrillator or ferromagnetic metal implants) **AND**
- Medical record documentation of continuing treatment with Aduhelm (aducanumab-avwa) based on recent MRI results as recommended in the FDA-approved package labeling (e.g. MRI to be obtained prior to the $5^{th}$, $7^{th}$, $9^{th}$, and $12^{th}$ infusions) **AND**
- Medical record documentation of repeat testing AND documented results of at least two of the following:
    - Mini-Mental State Examination (MMSE),
    - Montreal Cognitive Assessment (MoCA),
    - Clinical Dementia Rating-Global Score (CDR-GS),
    - Clinical Dementia Rating-Sum of Boxes (CDR-SB),
    - Repeatable Battery for the Assessment of Neuropsychological Status (RBANS), and/or
    - Quick Dementia Rating System (QDRS)
- Medical record documentation that member does not have any exclusions to treatment with Aduhelm (aducanumab-avwa), including all of the following:
    - A history of stroke or transient ischemic attack (TIA) or unexplained loss of consciousness in the past year AND

    - Poorly controlled diabetes mellitus AND
    - A brain MRI showing evidence of acute or sub-acute micro- or macro-hemorrhage, greater than 4 microhemorrhages, cortical infarct, or greater than 1 lacunar infarct AND
    - Current use of anticoagulants (except for aspirin at a prophylactic dose or less) **AND**
- Medical record documentation of a dose that is consistent with FDA-approved package labeling.

**Require RPH Sign off:** Yes

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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**Leqembi (lecanemab-irmb)**

**Review:** Leqembi is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease (AD). Treatment should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease (the population studied in clinical trials). There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. The indication was approved under accelerated approval based on the reduction in amyloid beta plaques observed, and continued approval may be based upon confirmation of clinical benefit in confirmatory trials. The recommended dose of Leqembi is 10mg/kg to be given over approximately one hour, once every two weeks. Leqembi is supplied in either one of two cartons. One carton (NDC 62856-215-01) contains one single-dose vial at a strength of 500mg/5mL (white cap). A second carton (NDC 62856-212-01) contains one single-dose vial at a strength of 200mg/2mL (dark grey cap). Leqembi is the second anti-amyloid monoclonal antibody approved for AD and the second drug approved to slow the progression of AD. The first anti-amyloid monoclonal antibody being Biogen's Aduhelm, which received a controversial approval in June 2021.

**Clinical Discussion:** Did clinical trials differentiate how they attributed brain volume loss due to Leqembi vs. the progressive nature of Alzheimer's disease. Study investigators are still unsure how to interpret the loss of brain volume. No comments or questions. The committee unanimously voted to accept the recommendations as presented.

**Financial Discussion**: The committee unanimously voted to accept the recommendations.

**Outcome:** Leqembi is a medical benefit managed by GHP and will require prior authorization. The following prior authorization will apply:

- Medical record documentation Leqembi (lecanemab-irmb) is prescribed by or in consultation with a dementia specialist (e.g., neurologist, psychiatrist, geriatric psychiatrist, neuropsychiatrist, geriatrician, or gerontologist) **AND**
- Medical record documentation that the dementia specialist will monitor the beneficiary at least once every 3 months **AND**
- Medical record documentation of a diagnosis of Mild Cognitive Impairment (MCI) due to Alzheimer's Disease (AD) or mild dementia due to Alzheimer's Disease (AD) [diagnosis codes may include: G30, G30.0, G30.1, G30.8, G30.9, G31.84] **AND**
- Medical record documentation of <u>no</u> medical or neurological conditions (other than Alzheimer's disease) that might be a significant contributing cause of the beneficiary's cognitive impairment **AND**
- Medical record documentation of <u>no</u> contraindications to Magnetic Resonance Imaging (MRI) (e.g. cardiac pacemaker/defibrillator or ferromagnetic metal implants) **AND**

- Medical record documentation of MRI obtained within one year prior to initiating treatment with Leqembi (lecanemab-irmb) **AND**
- Medical record documentation of positron emission tomography (PET) scan positive for brain amyloid plaques OR cerebrospinal fluid (CSF) biomarker testing positive for beta-amyloid plaques (as indicated by reduced amyloid beta 42 [Aβ42] levels OR reduced amyloid beta 42 amyloid beta 40 ratio [Aβ42/Aβ40 ratio] in CSF) **AND**
- Medical record documentation of at least <u>two</u> (2) of the following:
    - Mini-Mental State Examination (MMSE) score of greater than or equal to 22,
    - Montreal Cognitive Assessment (MoCA) score greater than or equal to 17,
    - Clinical Dementia Rating-Global Score (CDR-GS) of 0.5 or 1,
    - Clinical Dementia Rating-Sum of Boxes (CDR-SB) score less than or equal to 9,
    - Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) score less than or equal to 85, and/or
    - Quick Dementia Rating System (QDRS) score less than or equal to 12 **AND**
- Medical record documentation that member does <u>not</u> have any exclusions to treatment with Leqembi (lecanemab-irmb), including <u>all</u> of the following:
    - A history of stroke, transient ischemic attack (TIA), or seizures in the past year AND
    - A bleeding disorder that is not under adequate control (e.g. a platelet count <50,000 or international normalized ratio [INR] >1.5) AND
    - A brain MRI at screening showing <u>any</u> of the following significant pathological findings:
        - More than 4 microhemorrhages (defined as 10 millimeter [mm] or less at the greatest diameter),
        - A single macrohemorrhage >10 mm at greatest diameter,
        - An area of superficial siderosis,
        - Evidence of vasogenic edema,
        - Evidence of cerebral contusion, encephalomalacia, aneurysms, vascular malformations, or infective lesions,
        - Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease,
        - Space occupying lesions, and
        - Brain tumors (excludes lesions diagnosed as meningiomas or arachnoid cysts and less than 1 cm at their greatest diameter) **AND**
- Medical record documentation of a dose that is consistent with FDA-approved package labeling.

**GPI Level:** GPI-12
**Require RPH Sign off:** Yes
**Formulary Alternatives:** Aduhelm

**Authorization Duration & Reauthorization Criteria:** Approval will be given for an initial duration of **twelve (12) months** or less if the reviewing provider feels it is medically appropriate. After the initial twelve (12) month approval, subsequent approvals will be for a duration of **twelve (12) months** or less if the reviewing provider feels it is medically appropriate, and will require:

- Medical record documentation that member continues to experience medical benefit from and tolerability to Leqembi (lecanemab-irmb) based on the prescriber's assessment **AND**

- Medical record documentation Leqembi (lecanemab-irmb) is prescribed by or in consultation with a dementia specialist (e.g., neurologist, psychiatrist, geriatric psychiatrist, neuropsychiatrist, geriatrician, or gerontologist) **AND**
- Medical record documentation that the member was, and will continue to be, monitored and assessed by the prescribing dementia specialist at least every 3 months **AND**
- Medical record documentation of no medical or neurological conditions (other than Alzheimer's disease) that might be a significant contributing cause of the beneficiary's cognitive impairment **AND**
- Medical record documentation of no contraindications to Magnetic Resonance Imaging (MRI) (e.g. cardiac pacemaker/defibrillator or ferromagnetic metal implants) **AND**
- Medical record documentation of continuing treatment with Leqembi (lecanemab-irmb) based on recent MRI results as recommended in the FDA-approved package labeling (e.g. MRI to be obtained prior to the 5th, 7th, and 14th infusions) **AND**
- Medical record documentation of repeat testing AND documented results of at least two of the following:
    - Mini-Mental State Examination (MMSE),
    - Montreal Cognitive Assessment (MoCA),
    - Clinical Dementia Rating-Global Score (CDR-GS),
    - Clinical Dementia Rating-Sum of Boxes (CDR-SB),
    - Repeatable Battery for the Assessment of Neuropsychological Status (RBANS), and/or
    - Quick Dementia Rating System (QDRS) **AND**
- Medical record documentation that member does not have any exclusions to treatment with Leqembi (lecanemab-irmb), including all of the following:
    - A history of stroke, transient ischemic attack (TIA), or seizures in the past year AND
    - A bleeding disorder that is not under adequate control (e.g. a platelet count <50,000 or international normalized ration [INR] >1.5) AND
    - A brain MRI at screening showing any of the following significant pathological findings:
        - Evidence of cerebral contusion, encephalomalacia, aneurysms, vascular malformations, or infective lesions,
        - Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease,
        - Space occupying lesions, and
        - Brain tumors (excludes lesions diagnosed as meningiomas or arachnoid cysts and less than 1 cm at their greatest diameter); **AND**
- Medical record documentation of a dose that is consistent with FDA-approved package labeling.

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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**Rebyota (fecal microbiota, live-jslm)**

**Review:** Rebyota is the first fecal microbiome therapy to be approved for the prevention of recurrence of *Clostridium difficile* infections (CDI) in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI. Rebyota is not indicated for the treatment of CDI. Rebyota is manufactured from human fecal matter sourced from qualified donors. The human fecal matter is tested for a panel of transmissible pathogens. Donors do not have dietary restrictions with respect to potential food allergens. The fecal microbiota suspension is the filtrate generated by processing the fecal matter in a pre-defined ratio with a solution of polyethylene glycol (PEG) 3350

and saline. Each 150 ml dose is Rebyota contains between $1x10^8$ and $5x10^{10}$ colony forming units (CFU) per mL of fecal microbes including > $1x10^5$ CFU/mL of *Bacteroides*, and contains not greater than 5.97 grams of PEG 3350 in saline. The mechanism of action of Rebyota has not been established.

**Clinical Discussion:** The committee unanimously voted to accept the recommendations.

**Financial Discussion**: The committee unanimously voted to accept the recommendations.

**Outcome:** Rebyota will be a medical benefit managed by GHP. The following prior authorization criteria will apply:

- Documentation of age greater than or equal to 18 years AND
- Prescribed by or in consultation with an infectious disease specialist or gastroenterologist AND
- Medical record documentation that Rebyota will be used for the prevention of recurrence of *C. difficile* infections AND
- Medical record documentation of a diagnosis of recurrent *C. difficile* infection based on the results of an appropriate laboratory stool test within 30 days of prior authorization request AND
- Medical record documentation that an appriopriate standard-of-care antibacterial regimen was used for the treatment of recurrent *C. difficile* infection (e.g., oral fidaxomicin, oral vancomycin, oral metronidazole) AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Zinplava AND
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

**AUTHORIZATION DURATION:** If approved, authorization shall be for the authorization of one (1) Rebyota dose with an authorization duration of 30 days

**ATTENTION REVIEWER:** Rebyota is not indicated for the treatment of *C. difficile* infection infections. There is no information currently available indicating that an individual is unable to receive more than one dose of Rebyota.

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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**Tzield (teplizaumab-mzwy)**

**Review:** Tzield (teplizumab-mzwv) is indicated to delay the onset of Stage 3 Type 1 Diabetes (T1D) in adults and pediatric patients aged 8 years and older with Stage 2 T1D. Stage 2 T1D should be confirmed by documenting at least 2 positive pancreatic islet autoantibodies in those who have dysglycemia without overt hyperglycemia using an oral glucose tolerance test (OGTT) or alternative method if appropriate and OGTT is not available. If the patient meets the criteria for a diagnosis of Stage 2 T1D, providers should ensure that the clinical history of the patient does not suggest Type 2 Diabetes (T2D). Prior to initiation of Tzield, providers should obtain a complete blood count (CBC) and liver enzyme tests. Tzield is administered by intravenous (IV) infusion (over a minimum of 30 minutes) once daily for 14 days. Patients taking Tzield should be premedicated with: (1) a non-steroidal anti-inflammatory drug (NSAID) or acetaminophen, (2) an antihistamine, and/or (3) an antiemetic before each Tzield dose for at least the first 5 days of the 14-day treatment course.

**Clinical Discussion:** Do we need to add a note or authorization duration to ensure members are not approved for more than one dose per lifetime? Leslie and Keith will work together to craft language to include. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented.

**Financial Discussion**: The committee unanimously voted to accept the recommendations.

**Outcome:** Tzield will be a medical benefit managed by GHP. The following prior authorization criteria should apply:

1. Medical record documentation of a diagnosis of Stage 2 Type 1 Diabetes (T1D) confirmed by both of the following:
    a. Medical record documentation at least two positive pancreatic islet cell autoantibodies **AND**
    b. Medical record documentation of dysglycemia without overt hyperglycemia using an oral glucose tolerance test (OGTT) [if an OGTT is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be appropriate]

**AND**

2. Medical record documentation OR provider attestation that the clinical history of the patient does not suggest Type 2 Diabetes (T2D) **AND**
3. Medical record documentation that member is 8 years of age or older **AND**
4. Medical record documentation that Tzield is prescribed by or in consultation with an endocrinologist.

**NOTE TO REVIEWER:** Pancreatic Islet Autoantibodies include:

- Glutamic Acid Decarboxylase 65 (GAD) Autoantibodies
- Insulin Autoantibodies (IAA)
- Insulinoma-Associated Antigen 2 Autoantibodies (IA-2A)
- Zinc Transporter 8 Autoantibodies (ZnT8A)
- Islet Cell Autoantibodies (ICA)

**GPI Level:** GPI-12
**Authorization Duration:** Approval will be for 14 days. Authorization of Tzield should not exceed the FDA-approved treatment duration of 14 days. For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

**Formulary Alternatives:** None
**Require RPH Sign off:** Yes

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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**Korsuva (difelikefalin)**

**Review:** Korsuva is the first treatment for moderate-to-severe pruritis associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD). Currently, there are no formalized treatment guidelines for treatment of CKD-aP because of a lack of supportive evidence for use of currently utilized therapies.

**Clinical Discussion:** One member of the committee was opposed to the clinical recommendations, all other committee members voted to accept the recommendations.

**Financial Discussion**: The committee unanimously voted to accept the recommendations.

**Outcome:** Korsuva will be covered as a medical benefit and managed by GHP. No additional prior authorization criteria will apply:

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Korsuva is prescribed by a nephrologist AND
- Medical record documentation of moderate-to-severe pruritis associated with chronic kidney disease (CKD-aP) AND
- Medical record documentation that member is undergoing hemodialysis AND
- Medical record documentation that the member was assessed for and determined to have no other causes of pruritis

**GPI Level:** GPI-12

**Require RPH Sign off:** Yes

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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**Skysona (mosunetuzumab-axgb)**

**Review:** Skysona is indicated to slow the progression of neurologic dysfunction in male patients 4 to 17 years of age with early, active cerebral adrenoleukodystrophy (CALD). Early, active CALD refers to asymptomatic or mildly symptomatic (neurologic function score ≤1) males who have gadolinium enhancement on brain MRI and Loes scores of 0.5 to 9. Skysona was approved under the accelerated approval pathway, and continued approval will be based on longer term confirmatory trials. Adrenoleukodystrophy (ALD) is a rare genetic condition characterized by progressive loss of white matter in the nervous system and degradation of adrenal glands. It is caused by a mutation in the ABCD1 gene on the X chromosome. The diagnosis of ALD can be established based on clinical findings, elevated very-long-chain fatty acids (VLCFAs) and confirmed via genetic testing. CALD is a specific subtype of ALD, and the most severe and neurodegenerative form of the disease. Boys with CALD typically present with neurologic symptoms between 3 and 10 years old. After an initial period of normal development, symptoms typically include behavioral problems, such as ADHD and learning disabilities. Progressive symptoms include diminished visual acuity, hearing loss, gait instability, weakness and stiffness of limbs, and seizures. Within 2-3 years symptoms progress to a loss of most neurologic function and total disability, with death often occurring by the second decade of life. The overall prevalence of adrenoleukodystrophy is approximately 1 in 17,000 newborns. According to bluebird's estimates, about 40 patients are diagnosed with CALD in the United States each year.

**Clinical Discussion:** Even though this is an inpatient medication, it is likely we will be consulted for approval prior to administration which is why it is necessary to create a policy. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented.

**Financial Discussion**: The committee unanimously voted to accept the recommendations.

**Outcome:** Skysona will be a medical benefit, limited to administration in the inpatient hospital setting. Skysona will require a prior authorization with the following criteria.

- Prescription written by a hematologist, neurologist and/or stem cell transplant specialist AND
- Medical record documentation that the patient is a male based on assigned sex at birth, age greater than or equal to 4 years and less than or equal to 17 years AND
- Medical record documentation of a diagnosis of adrenoleukodystrophy (ALD) confirmed by BOTH of the following:
    - Medical record documentation of the presence of a mutation (variant) in the adenosine triphosphate binding cassette, sub family D member 1 (*ABCD1) gene* confirmed by genetic testing, AND
    - Medical record documentation of elevated plasma concentrations of very long chain fatty acids (VLCFA) levels AND
- Medical record documentation that the patient has early, active cerebral disease (Cerebral adrenoleukodystrophy (CALD)) as evidenced by ALL of the following:
    - Central radiographic review of Brain MRI demonstrating BOTH of the following:
        - Loes score between 0.5 and 9 (inclusive) on the 34-point scale AND
        - Gadolinium enhancement on MRI of demyelinating lesions AND
    - Neurologic function score (NFS) of less than or equal to 1 AND
- Medical record documentation that the member has not had a prior hematopoietic stem cell transplant AND
- Medical record documentation the member is a candidate for an allogenic hematopoietic stem cell transplant but ineligible due to absence of Human Leukocyte Antigen (HLA)-matched family donor* AND
- Medical record documentation that the member has not received Skysona, or any other gene therapy previously AND
- Medical record documentation that the member has a negative serology test for Human Immunodeficiency Virus (HIV) AND
- Medical record documentation that the member will have treatment administered at a Skysona Qualified Treatment Center

**Authorization Duration:** One (1) time approval per lifetime; Requests for authorizations exceeding these limits will require the following 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 beyond the FDA-approved treatment duration.

**Require RPH Sign off:** Yes

*Note to reviewer: The package insert recommends confirming that hematopoietic stem cell transplantation (HSCT) is appropriate prior to Skysona since patients will be going through similar steps (mobilization, apheresis, and myeloablation) required for a HSCT. However, the ALD-102 clinical trial excluded patients who had a known and available HLA-matched family donor. Considering that HSCT has been available for longer and has more evidence supporting its use, it may be appropriate to require HSCT as an alternate to Skysona. While it is possible for patients to have a matched unrelated donor, outcomes are best with matched related donors.

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

**Zynyz (mosunetuzumab-axgb)**

**Review:** Zynyz is a programmed death-receptor-1 (PD-1)- blocking antibody indicated for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma. This indication was an accelerated approval based on tumor response rate and duration of response. Zynyz binds the PD-1 receptor and blocks its interaction with the ligands PD-L1 and PD-L2 and potentiates T-cell activity. NCCN recommends Zynyz as single-agent treatment of locally advanced, region disease, and metastatic disease in patients who are not amenable to surgery or radiation therapy (Category 2A). The recommend dosage of Zynyz is 500 mg administered as an intravenous infusion over 30 minutes every 4 weeks until disease progression, unacceptable toxicity, or up to 24 months. There are no dosage reductions recommended. Zynyz can be withheld for severe (Grade 3) immune-mediated adverse reactions. It should be permanently discontinued for life-threatening (Grade 4) immune-mediated adverse reactions, recurrent severe (Grade 3) immune-mediated reactions that require systemic immunosuppressive treatment, or an inability to reduce corticosteroid dose to 10 mg or less of prednisone equivalent per day within 12 weeks of initiating steroids. Zynyz is available as a 500 mg/20 mL (25 mg/mL) in a single-dose vial.

**Clinical Discussion:** The committee unanimously voted to accept the recommendations.

**Financial Discussion**: The committee unanimously voted to accept the recommendations.

**Outcome:** Zynyz is a medical benefit that will be managed by GHP and will require a prior authorization. The following prior authorization criteria will apply:

- Medical record documentation that Zynyz is written by a hematologist or oncologist AND
- Medical record documentation of age greater than or equal to 18 years of age AND
- Medical record documentation of a diagnosis of metastatic or recurrent locally advanced Merkel cell carcinoma

**GPI Level:** GPI-12

**Authorization Duration:** 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. The medication will no longer be covered if patient experiences toxicity or worsening of disease**.**

**Require RPH Sign off:** Yes

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

**Xenpozyme (olipudase alfa-rpcp)**

**Review:** Xenpozyme is a hydrolytic lysosomal sphingomyelin-specific enzyme indicated for the treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients. Xenpozyme provides and exogenous from of the enzyme acid sphingomyelinase (ASM) which has reduced activity in ASMD cause by pathogenic variants in the sphingomyelin phosphodiesterase 1 gene. Xenpozyme is not

expected to cross the blood brain barrier and therefore is not likely to modulate CNS manifestations associated with ASMD

**Clinical Discussion:** The committee unanimously voted to accept the recommendations.

**Financial Discussion**: The committee unanimously voted to accept the recommendations.

**Outcome:** Xenpozyme is a medical benefit that will be managed by GHP and will require a prior authorization. The following prior authorization criteria should apply:

- Medical record documentation of a diagnosis of acid sphingomyelinase deficiency (ASMD) AND
- Medical record documentation of clinical presentation consistent with ASMD type B OR ASMD type A/B AND
- Medical record documentation of one of the following:
    - Documentation of sphingomyelin phosphodiesterase-1 (SMPD1) genetic mutation OR
    - Documentation of enzyme assay demonstrating a deficiency of acid sphingomyelinase activity

AND

- Medical record documentation that Xenpozyme will be used for the treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD)

**GPI Level:** GPI-12

**Authorization Duration:** Initial approval will be for **6 months**. Subsequent approvals will be for an additional **12 months** 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.

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**Hyftor (sirolimus)**

**Review:** Hyftor is an (mTOR) inhibitor immunosuppressant indicated for the treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older. All age-appropriate vaccinations recommended by current guidelines should be completed prior to Hyftor initiation. Hyftor is available as a topical 0.2% gel (2 mg of sirolimus per gram). The maximum daily dose is 600 mg (2 cm) for patients 6 to 11 years of age and 800 mg (2.5 cm) for patients 12 years of age and older.

**Clinical Discussion:** The committee unanimously voted to accept the recommendations.

**Financial Discussion**: The committee unanimously voted to accept the recommendations.

**Outcome:** Hyftor is a pharmacy benefit that will be managed by GHP and should be added to the GHP Family pharmacy formulary at the Brand tier. The following prior authorization criteria should apply:

- Medical record documentation of age 6 years or older **AND**
- Medical record documentation of a diagnosis of facial angiofibroma associated with tuberous sclerosis **AND**

- Medical record documentation of age appropriate dosing (less than or equal to 600 mg per day for patients 6 to 11 years of age OR less than or equal to 800 mg per day for patients 12 years of age and older).

**GPI Level:** GPI-12

**Day Supply Limit:** 30 days

**Authorization Duration (All LOB):** Initial approval will be for **3 months**.

**Reauthorization info:** Subsequent approvals will be for an additional **6 months** and will require medical record documentation of clinical improvement or lack of progression in symptoms of facial angiofibromas on Hyftor therapy is required.

**RPh Sign Off:** No

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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**Vivimusta & Belrapzo (bendamustine)**

**Review:** Vivimusta and Belrapzo are alkylating drugs indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) and adult patients with indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. Other than efficacy relative to chlorambucil, efficacy relative to other first line therapies for CLL has not been established.

**Clinical Discussion:** The committee unanimously voted to accept the recommendations.

**Financial Discussion**: The committee unanimously voted to accept the recommendations.

**Outcome:** Vivimusta and Belrapzo are medical benefits managed by GHP and should not require a prior authorization.

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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**Fast Facts**

N/A

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**Updates**

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**Budesonide and Formoterol Inhalation**

**Recommendation:** The newer GINA guidelines recommend for patients 12 years and older to use Symbicort as a rescue inhaler in addition to the BID dosing, SMART approach. SABAs are no longer preferred. For patients 6-11 years old, the reliever option can be as-needed SABA or as-needed ICS-formoterol. Budesonide-formoterol is the only agent indicated for this use in the guidelines, so they would be interested in this agent as a preferred product. Budesonide-formoterol for PRN use allows up to 12 inhalations per day. Also, from an Asthma Medication Ratio

(AMR) HEDIS measure perspective , the addition of budesonide-formoterol would potentially make a positive impact on the measure rates. Members would hopefully replace their SABAs with Symbicort and decrease their rescue inhaler fills, which would improve the AMR measure. To account for this dosing, it is recommended to increase the quantity limit for budesonide – formoterol inhalers to 1.02 grams per day

**Outcome:** The committee unanimously voted to accept the recommendation

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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**Medical Benefit Policy Update**

**Recommendation:** Based on DHS' feedback the age for Pedmark was changed to "greater than or equal to 1 month but less than or equal to 18 years of age"

**Outcome:** The committee unanimously voted to accept the recommendation

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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**Mifepristone**

**Recommendation:** It was recently identified that Geisinger is the only insurer offering Commercial coverage in the state of Pennsylvania which does not cover mifepristone as part of the drug formulary. Mifepristone is used in combination with misoprostol to terminate a pregnancy up to 70 days (10 weeks) gestation. Since its original approval in 2000, mifepristone has been used approximately 5.6 million times and the FDA has found it to have a very low rate of complications and a high rate of effectiveness. In order to ensure our members have access to mifepristone when deemed medically necessary, it is recommended that mifepristone is added to the Medicaid formulary on the generic tier.

**Outcome:** The committee unanimously voted to accept the recommendation

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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**May 2023 DUR/Adherence Update**

The May 2023 DUR/Adherence Update was presented to the Committee for review.

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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**April ELECTRONIC VOTE**

An electronic vote was held from April 14, 2023 to April 25, 20203. Responses were received from 32 members (out of 51 members) and all voted to approve. 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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**Elahere (mirvetuximab soravtansine-gynx) Drug Review**

**Review:** On November 14, 2022, the U.S. Food and Drug Administration (FDA) granted accelerated approval to ImmunoGen Inc.'s Elahere (mirvetuximab soravtansine-gynx) for the treatment of adult patients with folate receptor alpha (FRα)-positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. As with all FDA accelerated approvals, continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial.

**Outcome:** Elahere is a medical benefit that is managed by GHP. The following prior authorization criteria will apply:

- Medical record documentation that Elahere is prescribed by a hematologist or oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer AND
- Medical record documentation of the presence of folate receptor alpha (FRα) tumor expression as determined by an FDA-approved test* AND
- Medical record documentation of one to three prior systemic treatment regimen

**Authorization Duration:** 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. The medication will no longer be covered if patient experiences toxicity or worsening of diseases

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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Jemperli (dostarlimab-gxly)

Updated Indication: Jemperli (dostarlimab-gxly) has been granted full approval for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer (EC), as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen in any setting and are not candidates for curative surgery or radiation

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

<u>Endometrial Cancer</u>

1. Medical record documentation that Jemperli is prescribed by a hematologist or oncologist **AND**
2. Medical record documentation of age greater than or equal to 18 years **AND**
3. Medical record documentation of a diagnosis of recurrent or advanced endometrial cancer **AND**
4. Medical record documentation of mismatch repair deficient (dMMR) as determined by an FDA approved test **AND**
5. Medical record documentation of disease progression on or following prior treatment with a platinum-containing regimen **AND**
6. Medical record documentation that member is not a candidate for curative surgery or radiation

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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Opdivo (nivolumab)

Updated Indication: Opdivo is now indicated for use as a single agent or in combination with ipilimumab (Yervoy) for the treatment of unresectable or metastatic melanoma in adult and pediatric patients 12 years and older.

The following change is recommended to the Opdivo policy:
• Prescription written by a hematologist/oncologist AND
• Medical record documentation that patient is > 12 years of age AND
• Medical record documentation of one of the following:
    o A diagnosis of unresectable or metastatic melanoma AND
    o Opdivo is not being used in combination with any other agents for the treatment of unresectable or metastatic melanoma (with the exception of ipilimumab).

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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Trodelvy (sacituzumab govitecan)

Updated Indication: Trodelvy is now indicated for the treatment of adult patients with unresectable locally advanced or metastatic hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer who have received endocrine based therapy and at least two additional systemic therapies in the metastatic setting.

No changes recommended to the formulary placement or authorization duration of Trodelvy at this time. However, it is recommended to update policy MBP 216 to include the following changes:

**Unresectable Locally Advanced or Metastatic Triple-Negative Breast Cancer**

- Medical record documentation that Trodelvy is written by a hematologist/oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of diagnosis of unresectable locally advanced or metastatic triple-negative breast cancer* AND
- Medical record documentation of trial of at least two previous lines of systemic therapy, of which at least one was for metastatic disease

*Note: Triple negative breast cancer lacks expression of estrogen receptor (ER-negative), progesterone receptor (PR-negative) and human epidermal growth factor receptor 2 (HER2-negative).

**Unresectable Locally Advanced or Metastatic HR Positive, HER2 Negative Breast Cancer**

- Medical record documentation that Trodelvy is written by a hematologist/oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of diagnosis of unresectable locally advanced or metastatic hormone receptor (HR)positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer AND
- Medical record documentation of previously receiving endocrine-based therapy AND
- Medical record documentation of previously receiving at least two additional systemic therapies in the metastatic setting

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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GHP Family Update

Discussion: During a recent review of policies by DHS it was requested that the change noted below be made to be consistent with the drug's indication.

Recommendation: It is recommended the Committee approve the change:

- Medical record documentation that Verquvo is prescribed by or in consultation with a cardiologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of symptomatic chronic New York Heart Association Class II-IV heart failure **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of hospital admission due to heart failure within the previous 6 months **OR**
    - Medical record documentation of outpatient intravenous (IV) diuretic treatment for heart failure within the previous 3 months

**AND**

- Medical record documentation of a left ventricular ejection fraction (LVEF) ~~less than or equal to~~ < 45% **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one formulary angiotensin converting enzyme inhibitor (ACEi), angiotensin receptor blocker (ARB) or angiotensin receptor and neprilysin inhibitor (ARNI) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one formulary beta-blocker **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

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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Medical Benefit Generic Drug Update (applicable to non-PDL meds only)

Discussion: All current medical benefit drug policies were reviewed and drugs that have a therapeutically equivalent generic available were identified. Currently, there is no language in medical benefit drug policies requiring the use of a generic formulation first before the use of a brand formulation. When a medical benefit authorization is entered into Darwin, there is no limitation on whether a generic or brand can be filled by the specialty vendor. Using a generic drug first may provide cost savings for Geisinger Health Plan especially if a medication is being fulfilled by a specialty pharmacy. It is recommended to require a generic first before the use of a brand, when the generic formulation is available.

**Recommendation:** It is recommended that the following wording be added to applicable medical benefit policies for drugs that have a therapeutically equivalent generic available. Approvals for these drugs will also include "generic only" language when entered into the pharmacy claims processing system. The medical benefit list of drugs will be reviewed annually to identify drugs with newly released generic formulations. Policies identified upon annual review containing drugs with therapeutically equivalent generics will be automatically updated with the below language without further P&T committee review.

AND (if a brand drug is being requested when a therapeutically equivalent generic drug exists):
• Medical record documentation of a therapeutic failure on, or intolerance to the generic formulary agent(s) OR
• Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to the inactive ingredients of the generic formulary agent(s)

**List of Drugs with Available Therapeutically Equivalent Generic Formulations**

- Velcade (bortezomib)
- Aloxi (palonosetron)-Brand discontinued
- Abraxane (paclitaxel-protein bound)
- Clolar (clofarabine)
- Boniva (ibandronate) IV-Brand discontinued
- Flolan or Veletri (epoprostenol)
- Remodulin (treprodtinil)
- Arranon (nelarabine)
- Torisel (temsirolimus)
- Istodax (romidepsin)
- Emend (fosaprepitant)
- Tepadina (thiotepa)
- Trisenox (arsenic trioxide)

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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Meeting adjourned at 4:15 pm

**Future Scheduled Meetings**
The next bi-monthly scheduled meeting will be held on July 18, 2023 at 1:00 p.m.

Meetings will be held virtually via phone/Microsoft Teams