P&T Committee Meeting Minutes
Medicaid
January 17, 2023

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Kristen Bender, Pharm.D.
Amir Antonius, Pharm.D.	Holly Bones, Pharm.D.
Emily Antosh, Pharm.D.	Alyssa Cilia, RPh
Jeremy Bennett, MD	Michael Evans, RPh
Kim Castelnovo, RPh	Nichole Hossler, MD
Kimberly Clark, Pharm.D.	Jason Howay, Pharm.D.
Rajneel Farley, Pharm.D.	Jonas Pearson, RPh
Kelly Faust Pharm.D.	Michael Shepherd, MD
Tricia Heitzman, Pharm.D.	
Emily Hughes, Pharm.D.	
Keith Hunsicker, Pharm.D.	
Kelli Hunsicker, Pharm.D.	
Derek Hunt, Pharm.D.	
Kerry Ann Kilkenny, MD	
Philip Krebs, R.EEG T	
Briana LeBeau, Pharm.D.	
Ted Marines, Pharm.D.	
Lisa Mazonkey, RPh	
Tyreese McCrea, Pharm.D.	
Perry Meadows, MD	
Jamie Miller, RPh	
Mark Mowery, Pharm.D.	
Austin Paisley, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Melissa Renn, Pharm.D.	
Melissa Sartori, Pharm.D.	
Angela Scarantino	
Kristen Scheib, Pharm.D.	
William Seavey, 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 (non-voting participant)	
Mallory Ellis, Pharm.D. (Pharmacy Resident)	

Call to Order:
Dr Yarczower called the meeting to order at 1:02 p.m., Tuesday, January 17, 2023

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Yarczower asked for a motion or approval to accept the November 15, 2022 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Terlivas (terlipressin)

Review: Terlivaz is a vasopressin receptor agonist indicated to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function. Patients with a serum creatinine > 5 mg/dL are unlikely to experience benefit. The American Association for the Study of Liver Diseases issued a guidance statement in 2021 recommending terlipressin in combination with albumin as first-line therapy. In settings where terlipressin is not available, norepinephrine should be given.

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

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

Outcome: Terlivaz is not currently a Medicaid rebatable drug. For that reason, Terlivaz will be excluded on the GHP Family formulary. When Terlivaz becomes Medicaid rebatable, it is recommended that Terlivaz will be a medical benefit that will be 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 a hepatologist or nephrologist AND
- Medical record documentation of a diagnosis of hepatorenal syndrome causing a rapid reduction in kidney function AND
- Medical record documentation of a serum creatinine less than or equal to 5.0 mg/dL AND
- Medical record documentation that Terlivaz will be given in combination with intravenous albumin OR intolerance or contraindication to albumin AND
- Medical record documentation that the patient does NOT meet any of the following conditions:
    - Baseline oxygen saturation (SpO_2) less than 90% OR
    - Volume overload OR
    - Acute-on-chronic liver failure (ACLF) Grade 3 OR
    - Ongoing coronary, peripheral, or mesenteric ischemia

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*:* Approval will be for up to 14 days of treatment and the authorization duration will be sufficient to cover the complete treatment course. Subsequent authorizations will be considered using the criteria outlined above.

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

Seysara (sarecycline)

Review: Seysara is FDA approved for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients >9 years of age.

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

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

Outcome: Seysara is a pharmacy benefit and currently is not managed by the PDL, it will be managed by GHP. Seysara is a non-rebateable/manufacturer is non-participating and should not be added to formulary. No additional prior authorization criteria should apply.

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

Tecvayli (teclistamab-cqyv)

Review: Tecvayli is a first-in-class T cell–redirecting, bispecific antibody targeting both B-cell maturation antigen (BCMA) and cluster of differentiation 3 (CD3) that is administered weekly as an "off-the-shelf" subcutaneous (SC) treatment. As a ready-to-use therapy, it has numerous advantages over competitor products, such as CAR-T products, which may take 4 weeks or longer to produce and administer. Tecvayli is Janssen's fourth FDA-approved treatment for multiple myeloma. The accelerated approval of Tecvayli is supported by results from the Phase 1/2 MajesTEC-1 trial, which included 110 patients who received a median of five prior lines of therapy.

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

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

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

- Medical record documentation that Tecvayli is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years old **AND**
- Medical record documentation of a diagnosis of relapsed or refractory multiple myeloma **AND**
- Medical record documentation of treatment with at least four (4) prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

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 6 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 the member experiences unacceptable toxicity or worsening of disease.

Formulary Alternatives: Revlimid*, Pomalyst*, bortezomib*, Kyprolis*, Ninlaro*, Darzalex*, Empliciti*, Farydak*, Sarclisa*, Xpovio* *Prior authorization required

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

Imjudo (tremelimumab-actl)

Review: Imjudo is a cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) blocking antibody indicated in combination with Imfinzi (durvalumab) for the treatment of adult patients with unresectable hepatocellular carcinoma. It also is indicated in combination with Imfinzi and platinum-based chemotherapy for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with no sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations. Imjudo binds CTLA-4, a negative regulator of T-cell activity and blocks the CTLA-4 mediated inhibition of T-cell activation. In mouse tumor models, blocking CTLA-4 resulted in decreased tumor growth and increased proliferation of T-cells in tumors. The recommended dosage of Imjudo for hepatocellular carcinoma is a single intravenous infusion administered on Day 1, Cycle 1, with Imfinzi followed by Imfinzi monotherapy every 4 weeks until disease progression or unacceptable toxicity. The dosage is based on body weight. For patients weighing 30 kg or more, a single dose of Imjudo 300 mg is administered while patients weighing less than 30 mg should receive an Imjudo dosed of 4 mg/kg. The recommended dosage and schedule of Imjudo for the treatment of metastatic non-small cell lung cancer is based on patient's weight and tumor histology

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

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

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

uHCC

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Imjudo is prescribed by a hematologist or oncologist AND
- Medical record documentation of unresectable hepatocellular carcinoma (uHCC) AND
- Medical record documentation that Imjudo will be used in combination with durvalumab (Imfinzi)

Metastatic NSCLC

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Imjudo is prescribed by a hematologist or oncologist AND
- Medical record documentation of metastatic non-small cell lung cancer (NSCLC) AND
- Medical record documentation no sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations AND
- Medical record documentation that Imjudo will be used in combination with durvalumab (Imfinzi) and platinum-based chemotherapy

Authorization Duration: For the treatment of unresectable HCC, approval will be given for a one time dose of Imjudo (not to exceed 300 mg) for a duration of 1 month. Authorization of Imjudo for the treatment of unresectable HCC should not exceed the FDA-approved treatment of one dose. 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

For the treatment of metastatic NSCLC, the approval of Imjudo will be for 6 months. Authorization of Imjudo for the treatment of metastatic NSCLC should not exceed the FDA-approved treatment duration of 16 weeks. 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

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

Fast Facts

Imfinzi (durvalumab)

New Indication: Imfinzi is now indicated in combination with tremelimumab-actl (Imjudo) for the treatment of adult patients with unresectable hepatocellular carcinoma and in combination with tremelimumab-actl (Imjudo) and platinum-based chemotherapy for the treatment of adult patients with metastatic non- small cell lung cancer (NSCLC) with no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations. Imfinzi has one additional new indication for treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC) in combination with gemcitabine and cisplatin.

The recommended doses for Imfinzi for the new indications are based on weight with varying durations and regimens dependent on disease state.

Recommendation: No changes are recommended to the formulary placement of Imfinzi. The following changes to the authorization duration and additional prior authorization criteria are recommended to incorporate the new indications for Imfinzi. It is also recommended that the Authorization Duration for Stage III NSCLC be updated to one approval of 12 months based on NCCN guidance which does not recommend routine surveillance MRI for Imfinzi for Non-small cell lung cancer

1. **Stage III Non-Small Cell Lung Cancer (NSCLC)**
   - Prescription written by a hematologist/oncologist **AND**
   - Medical record documentation that patient is 18 years of age or older **AND**
   - Medical record documentation of a diagnosis of unresectable Stage III Non-Small Cell Lung Cancer (NSCLC) **AND**
   - Medical record documentation that patient has received and has not progressed following a minimum of two cycles of concurrent platinum-based chemotherapy **AND** radiation therapy

AUTHORIZATION DURATION (Stage III NSCLC): One approval for 12 **months** or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Imfinzi for the treatment of non-small cell lung cancer should not exceed the FDA-approved treatment duration of 1 year (12 months). 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

2. Metastatic Non-Small Cell Lung Cancer (NSCLC)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of metastatic non-small cell lung cancer (NSCLC) AND
- Medical record documentation no sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations AND
- Medical record documentation that Imfinzi will be used in combination with tremelimumab-actl (Imjudo) and platinum-based chemotherapy

AUTHORIZATION DURATION (Metastatic NSCLC): 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.

3. Extensive-Stage Small Cell Lung Cancer (ES-SCLC)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis extensive-stage small cell lung cancer (ES-SCLC)* **AND**
- Medical record documentation that Imfinzi will be used as first-line treatment **AND**
- Medical record documentation that Imfinzi will be used in combination with etoposide and either carboplatin or cisplatin

*Note: The National Comprehensive Cancer Network (NCCN) Guidelines defines small cell lung cancer as consisting of two stages:

Limited Stage: Stage I-III (T any, N any, M0) that can be safely treated with definitive radiation doses. Excludes T3-4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan.

Extensive Stage: Stage IV (T any, N any, M1a/b), or T3-4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan

AUTHORIZATION DURATION (ES-SCLC): 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.

4. Unresectable Hepatocellular Carcinoma (uHCC)

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Imjudo is prescribed by a hematologist or oncologist AND

- Medical record documentation of unresectable hepatocellular carcinoma (uHCC) AND
- Medical record documentation that Imfinzi will be used in combination with tremelimumab-actl (Imjudo)

AUTHORIZATION DURATION (uHCC): 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.

5. **Biliary Tract Cancer (BTC)**
   - Medical record documentation of age greater than or equal to 18 years AND
   - Medical record documentation that Imjudo is prescribed by a hematologist or oncologist AND
   - Medical record documentation of locally advanced or metastatic biliary tract cancer (BTC) AND
   - Medical record documentation that Imfinzi will be used in combination with gemcitabine and cisplatin

AUTHORIZATION DURATION (BTC): 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.

Outcome: The committee unanimously voted to accept the recommendations.

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

Updates

January 2023 DUR Report

Recommendation: It is recommended to accept the presentation of the January 2023 DUR Report.

Drug Use Evaluations (DUEs)

- Overutilization of albuterol and levalbuterol
  - This is our 2022 3rd quarter Geisinger Health Plan DUE for Commercial, Exchange, Medicaid, Chip
  - For this report, we identified members who had greater than a 180-day cumulative day supply of Albuterol and/or levalbuterol (based on pharmacy claims from 1/1/2022-12/23/22) with a diagnosis of Asthma (based on medical claims from 4/1/2021 through 12/23/22)
    - **1168 members** were identified with overutilization of their inhalers
    - Letters were sent to the MI attributed PCP of each member with their medication fill history of both their controller and rescue inhalers to help providers identify members that may be overutilizing their rescue inhalers and to identify potential compliance concerns with their controller inhaler.
    - We will be re-running this data in June 2023 to analyze effectiveness of the letter
- Use of Opioids at High Dosage

- This is our 2022 2nd quarter Geisinger Health Plan DUE for Commercial, Exchange, TPA, Medicaid, Medicare
- From this report, we identified members 18 years and older with 15+ opioid covered days and had an MME of 90 or greater per day based on claims from 1/1/2022 through 7/27/2022
  - **84 members** were identified with an MME of 90 or greater
  - Letters were sent to the MI attributed PCP of each member with the respective medication fill history for providers to evaluate their patients current pain regimen and ensure lowest effective doses are utilized.
  - Letters were mailed out on 9/15/2023
  - We will be re-running this data in January 2023 to analyze effectiveness of the letter.

- Asthma Medication Ratio
  - This is our 2022 1st quarter Geisinger Health Plan DUE for Commercial, Exchange, Medicaid, CHIP
  - From this report, we used proactive HEDIS data and identified members aged 5-64 with an AMR<0.5. Pharmacy claims from the prior 6 months (9/2021-3/2022) were pulled into the report.
    - **202 members** were identified with an AMR<0.5
    - Letters were sent to the MI attributed PCP of each member with the respective medication fill history to encourage conversation around the importance of controller medications.
  - Letters were mailed out on 4/20/2022
  - Adam K. re-ran this data on 8/29/2022 to analyze the effectiveness of the letter. Of the 202 members initially identified, 162 members were still active. Of those members, **74 members** showed an AMR increase compared to 4/2022.
- Use of Opioids from Multiple Providers (UOP) DUE
  - This is our 2021 3rd quarter Geisinger Health Plan DUE for Medicare, Medicaid, and Commercial
  - From this report, we identified members 18 years of age and older with a total day supply of all opioid claims to be 15 days or greater based on claims from 1/1/2021 through 9/27/2021:
    - **49 members** were identified who were seeing 4 or more providers from different offices for their opioid prescriptions
    - **11 members** were identified who were seeing 4 or more providers within the same office for their opioid prescriptions
    - We sent letters to the MI attributed PCP of each member with the respective medication fill history to encourage medication evaluation of the opioid medications
  - Mitch Kocen completed the mail merge via Quadient on 10/14/2021 and the print shop sent out the letters on 10/18/2021
  - Adam K. re-ran this data on 3/10/2022 to analyze the effectiveness of the letter. Of the 60 members initially addressed, 54 members were still active. Of those members, **52 members** showed a decrease in the number of prescribers they were seeing compared to 10/2021
- Statin Use in Persons with Diabetes DUE
  - This is our 2021 2nd quarter Geisinger Health Plan DUE for all LOBs
  - From this report, we identified **1909 members** age 40 to 75 with at least 2 distinct fills of any diabetic medication(s) without a statin claim. We sent an educational letter to providers to encourage prescribing of a statin to members, if medically appropriate.
  - The Print Shop completed the mail merge and sent out letters to the member's providers on 8/2/2021.
  - Adam K. re-ran this data on 11/19/2021 to analyze the effectiveness of the letter. Of the 1909 members initially addressed, **1,827** are still active. Of those members, **217** now have a claim for a statin medication. This equates to about **12%** of the targeted members.

In Progress

- **No reports at this time.**

Ongoing

- Cystic Fibrosis Adherence Report
  - We get this report **monthly** for **all LOBs** from Adam Kelchner. The report identifies patients who have a specific diagnosis of Cystic Fibrosis & outpatient/office visits within the past 2 years. Further the report calls out medication fill history for specific CF medications and the corresponding PDC.
    - For those members who are seen by a GHS provider we send their information to the CF coordinators to discuss their medication adherence with the member
    - We send letters to non-GHS providers with the CF medication fill history for those members with a PDC less than 80%
    - And for all members we send a letter discussing the importance of medication adherence
    - For MANE in 2022, we sent **177 members** an adherence letter
      - Letters are only sent to members every 6 months
      - There were 3 **members** who saw a non-GHS pulmonologist and a letter was sent tfo that pulmonologist
      - There were **528 members** who saw GHS pulmonologists and were sent to the CF coordinators for follow up
- Duplicate Specialty Therapy
  - We run an in-house retrospective report **quarterly** for **all LOBs** with help from Adam Kelchner and Aubrielle Smith. These members are identified and written up and sent to a medical director if follow up is needed.
    - For MANE in 2022, we reviewed all 2022 data and **0 members** were referred to Dr. Yarczower for additional follow-up.
- Duplicate Buprenorphine Therapy
  - We get this report **quarterly** with help from Adam Kelchner. The report works to identify members who have at least a 7 day overlap period of generic Buprenorphine and generic Buprenorphine/naloxone products. Members identified as being on both products are being forwarded to Dr. Meadows and Dr. Hossler for further outreach.
    - For MANE in 2022, we have reviewed **12 members** and **3 members** were referred to Dr. Meadows
- Suboxone with an Opioid Report
  - We get this report **weekly** for **all LOBs** from Adam Kelchner and we are writing up each new member that flags on the report. These members are being discussed at our weekly meeting with Dr. Meadows and Dr. Hossler. Both medical directors look into whether it is appropriate to end the opioid authorizations still in place or if further intervention is required.
    - For MANE in 2022, we have reviewed **82 new members**, and **13 members** were referred to MDs for discussion
- Ending Opioid Authorizations
  - We are working on identifying members who have active opioid authorizations in place but have since started Buprenorphine therapy. The letter is sent to the members notifying them the opioid authorization has been ended due to the start of buprenorphine therapy.
    - For MANE in 2022, we sent **7 members** a letter notifying them of the end of their opioid authorization(s).
- Opioid Overutilization Report
  - We get this report **monthly** from PerformRx and we write up each member that flags on the report. We have been monitoring the members that are continuously showing up on the report by any change in their MED. For those members we deem appropriate we will send a letter to their PCP.
    - For MANE in 2022, we have reviewed **4 members**, referred **1 member** to MDs, and did not send any prescriber letters.

- FWA Reports
    - We get this report **weekly** for **all LOBs** from Jeremy Baker. We prepare this report by determining which claims need to be verified, and our GHP technician makes calls to pharmacies to correct/verify claims.
    - We review claims for anti-hypertensives, statins, 1-day supply, and inhalers
        - For MANE in 2022, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $11,690.44**
- Severity Report
    - This is a **monthly** report for **all LOBs** on members who have filled a medication that has a level one interaction with another medication they have a claim for
        - For MANE in 2022, letters have been sent to MI attributed providers of **952 GHP Family members**
- Tobacco Cessation Program
    - We get this report **monthly** to identify members on prolonged tobacco cessation treatment. We send a letter and resource pamphlet to provide additional behavioral health support through Geisinger Health and Wellness.
        - For MANE in 2022, we sent **157 letters** to encourage members to quit and provided resources for tobacco cessation.
- Antipsychotic with Opioid Report
    - We get this report **quarterly** to identify **Medicaid** members with an overlap of 8 or more days between an opioid and antipsychotic medication.
    - We send a letter with claims data to both the opioid prescriber and the antipsychotic prescriber to encourage collaboration in medication management.
        - For MANE in 2022, we have sent **362 letters** to **opioid prescribers** and **343 letters** to antipsychotic prescribers regarding a total of **427 members**
- STENT Adherence Report
    - We get this report **monthly** to identify members on an antiplatelet medication and then flag for betablocker and statin medication claims.
        - For MANE in 2022, we have sent letters encouraging adherence to:
            - **361 members for Antiplatelet**
            - **496 members for Beta-blocker**
            - **557 members for Statin**
        - *member may flag for more than one measure and are included in the count for each measure
    - For MANE in 2022, we have attempted telephonic outreach to **56 members** non-adherent in all 3 measures and reached **17 members** to encourage adherence.

- **HEDIS Initiatives: *Using proactive HEDIS data***
- Asthma Medication Ratio (AMR) Member Letters
    - Jesse Barsh runs this proactive HEDIS report **monthly,** and we send letters to the flagged members who have a ratio of controller to total asthma medications of < 0.5.
        - For MANE in 2022, we have sent letters to **446 members** to encourage adherence.
- Asthma Medication Ratio (AMR) Member Calls
    - Adam Kelchner runs this report **weekly** based off of proactive HEDIS reporting. we send Medicaid members 30 years of age and under who have had a controller or reliever medication filled in the past 3 months AND are past due for their controller medication to the Respiratory Therapists for direct telephonic outreach.
        - For MANE in 2022, we have referred **430 members** to the Respiratory Therapists for outreach.

        - For MANE In 2022, our pharmacy technician has outreached to **280 members** and reached **74 members**
- Antidepressant Medication Management (AMM)
    - Jesse Barsh runs this proactive HEDIS report **monthly,** and we send letters to the flagged members who appear non-adherent to their antidepressant medications.
        - For MANE in 2022, we have sent letters to **32 members** in the **Effective Acute Phase** and letters to **1,168 members** in the **Effective Continuation Phase** to encourage adherence.
- Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
    - Jesse Barsh runs this proactive HEDIS report **monthly,** and we send letters to the flagged members who appear non-adherent to their antipsychotic medications.
        - For MANE in 2022, we have sent letters to **112 members** to encourage adherence**.**
- Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - We get this report **monthly** to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
        - For MANE in 2022, we have sent letters to **188 providers** to encourage statin therapy
        - For MANE in 2022, we have sent letters to **136 members** to encourage statin adherence.
- Statin Therapy for Patients with Diabetes (SPD)
    - We get this report **monthly** to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
        - For MANE in 2022, we have sent letters to **993 providers** to encourage statin therapy
        - For MANE in 2022, we have sent letters to **136 members** to encourage statin adherence.
- Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)
    - We get this report **monthly** to identify members with a diagnosis of AMI who received beta-blocker treatment for 6 months after discharge and who are non-adherent to beta-blocker therapy
        - For MANE in 2022, we have sent letters to **9 members** to encourage beta-blocker therapy adherence.
- Use of Opioids from Multiple Providers (UOP)
    - We get this report quarterly to identify members 18 years of age and older with a total day supply of all opioid claims to be 15 days or greater
        - For MANE in 2022, **60 members** were identified who were seeing 4 or more providers from different offices for their opioid prescriptions
        - For MANE in 2022, **11 members** were identified who were seeing 4 or more providers within the same office for their opioid prescriptions
        - We sent letters to the MI attributed PCP of each member with the respective medication fill history to encourage medication evaluation of the opioid medications
            - *One letter every 6 months*

Fliers/Letters

- Medicaid DUR/FWA Program Internal Fliers
    - Last updated 11/2022 next update 6/2023
- Current Provider Letters
        - Cystic Fibrosis Adherence Letter
        - Congestive Heart Failure DUE
        - Coronary Artery Disease DUE
        - Statin Use in Persons with Diabetes DUE
        - Opioid Overutilization
        - Severity Report
        - Antipsychotic with Opioid Report
        - HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
        - HEDIS: Statin Therapy for Patients with Diabetes (SPD)
        - HEDIS: Asthma Medication Ratio (AMR)

    - HEDIS: Use of Opioids from multiple providers (UOP)
    - HEDIS: Use of Opioids at High Dosage (HDO)
- Current Member Letters
    - Cystic Fibrosis Adherence Letter
    - Ending Opioid Authorizations
    - Tobacco Cessation Letter
    - STENT Adherence Report
    - HEDIS: Asthma Medication Ratio (AMR)
    - HEDIS: Antidepressant Medication Management (AMM)
    - HEDIS: Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
    - HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - HEDIS: Statin Therapy for Patients with Diabetes (SPD)
    - HEDIS: Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)

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.

2023 GHP Family Formulary

Recommendation: The 2023 GHP Family Supplemental Formulary was submitted to the Committee for review. The recommendation was to approve the Formulary as presented.

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.

December ELECTRONIC VOTE

An electronic vote was held from December 15, 2022, to December 23, 2022. Responses were received from 33 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.

Benlysta (belimumab**)**

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

There are no recommended changes to the formulary status of Benlysta. The following changes are recommended to both the medical and pharmacy policy:

Systemic Lupus Erythematosus:

- Medical record documentation of age ≥ 18 years
- Medical record documentation of ~~active~~ systemic lupus erythematosus **AND**

- Medical record documentation that patient has active disease OR recurrent flares OR inability to wean steroids in systemic lupus erythematosus **AND**
- Positive ANA and/or anti-dsDNA antibody **AND**
- ~~Concurrently receiving a stable treatment regimen with prednisone, NSAID, anti-malarial, or immunosuppressant **AND**~~ Medical record documentation that Benlysta is being used in combination with, or patient has a contraindication or intolerance to, standard therapy (e.g. corticosteroid, NSAID, anti-malarial or immunosuppressant); **AND**
- No CNS involvement **AND**
- Prescribed by a rheumatologist **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

Lupus Nephritis:

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

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Libtayo (cemiplimab-rwlc)

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

It is recommended the highlighted update be made to the medical policy:
Non-Small Cell Lung Cancer (NSCLC)

- Prescription written by a hematologist or oncologist **AND**
- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of non-small cell lung cancer (NSCLC) **AND** medical record documentation of one of the following:
    - Documentation of locally advanced disease AND the patient is not a candidate for surgical resection or definitive chemoradiation **OR**

- Documentation of metastatic disease

AND

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

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

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Adcetris (Brentuximab vedotin)

Updated Indication: Adcetris is a CD30-directed antibody-drug conjugate that is now indicated for the treatment of previously untreated high risk classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide in pediatric patients aged 2 years and older.

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

Classical Hodgkin Lymphoma (cHL)

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

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

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

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

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

AUTHORIZATION DURATION:

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

Orkambi (ivacaftor/lumacaftor)

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

There are no changes to the formulary status. However, it is recommended to update the age restriction to ≥ 1 years

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Amvuttra Update

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

Amvuttra will be covered as a medical benefit for GHP Family members and will be managed by GHP. It is

recommended that Amvuttra require a prior authorization to ensure appropriate utilization. The following prior authorization criteria should apply.

Prior Authorization Criteria:

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

Note:

FAP stage:

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

Polyneuropathy disability score:

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

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

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

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

Dacogen Update

Discussion: Dacogen (decitabine) is indicated for the treatment of myelodysplastic syndromes (MDS). The Dacogen policy currently requires failure of Vidaza before approval of Dacogen for the diagnosis of MDS. NCCN guidelines do not prefer one agent to be used over another when a patient has higher risk MDS and is a transplant

candidate. In addition, the FDA prescribing information for Dacogen does not require failure of Vidaza within the indication. Therefore clinically, Vidaza is not required to be used prior to Dacogen use in MDS.

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

Synagis Update

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

The following will be added to the policy: "In the event of an atypical RSV season (ie. unpredicted, early or late, high rates of RSV circulation), listed indications may also be met on dates deemed appropriate by Geisinger Health Plan in conjunction with guidance from the American Academy of Pediatrics (AAP) and other applicable clinical resources."

Enhertu Update

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

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

It is recommended that the highlighted update be made to the criteria:
Breast Cancer

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

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

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

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

Meeting adjourned at 4:15 pm

Future Scheduled Meetings
The next bi-monthly scheduled meeting will be held on March 21, 2023 at 1:00 p.m.

Meetings will be held virtually via phone/Microsoft Teams