P&T Committee Meeting Minutes
Medicaid
March 17, 2020

Present: All voting done electronically.	**Absent: All voting done electronically.**

Call to Order:
Voting was held electronically from Tuesday, March 17, 2020 to March 24, 2020

Review and Approval of Minutes, Reviews, Fast Facts, and Updates:
Approved based on approval from 23 (out of 35 members), no members voted to reject.

DRUG REVIEWS

The following quantity limits were presented and approved:

Drug	**Dosage Form and Strength**	**Formulary Therapeutic Recommendation**
Vumerity	Capsules	Add QL: 4 capsules per day, 30 day supply per fill
Ayvakit	Tablet	Add QL: 1 tablet per day, 30 day supply per fill
Wakix	Tablet	Add QL: 2 tablets per day
Tazverik	Tablet	Add QL: 240 tablets per 30 days
Nourianz	Tablet	Add QL: 1 tablet per day
Inbrija	Capsule / Inhaler	Add QL: 10 capsules per day (5 boxes per month)
Entresto	Tablet	Update QL: 24/26 mg tablets: 6 tablets per day, 49/51 mg tablets: 3 tablets per day, 97/103 mg tablets: 2 tablets per day
Baxdela	Tablet	Update QL: 2 tablets per day, ABSSSI: 14 days CABP:10 days

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

Enhertu (fam-trastuzumab deruxtecan-nxki)

Review: Patients with unresectable or metastatic HER2-positive breast cancer who progress on first line-treatment regimens which typically include the HER2-antibody trastuzumab, have few treatment options for subsequent therapy. Enhertu, which combines trastuzumab with a topoisomerase inhibitor (DXd), binds the HER2 receptor causing the internalization and release of membrane permeable DXd which leads to DNA damage and cell death.

The efficacy of Enhertu was evaluated in DESTINY-Breast01, a single-arm, open-label study in 184 adult female patients with HER2-positive unresectable and/or metastatic breast cancer who have received two or more prior HER2-directed therapies. Part 1 of the study investigated pharmacokinetics and dosing, finding that 5.4 mg/kg provided the best balance between efficacy and safety. This was continued in patients until disease progression or unacceptable toxicity. Part 2 of the study evaluating efficacy showed a 60.9% overall response rate, including confirmed complete (6%) and partial responses (54.9%) (RECIST v 1.1.). Secondary endpoints showed a median duration of response of 14.8 months and progression free survival of 16.4 months. The estimated overall survival was 93.9% at 6 months and 56.2% at 12 months, but the median overall survival was not reached at the time of analysis.

Enhertu contains black box warnings for both interstitial lung disease (ILD) and the possibility of fetal embryo harm. In clinical trials, interstitial lung disease occurred in 9% of patients leading to fatal outcomes due to ILD and/or pneumonitis in 2.6% of patients. Enhertu should be discontinued in any patients with Grade 2 or higher symptomatic interstitial lung disease. In clinical trials of Enhertu, serious adverse reactions were reported in 20% of patients. Permanent discontinuation due to adverse reactions occurred in 9% of patients, 6% resulting from ILD. The most common adverse reactions were nausea, vomiting, fatigue, alopecia, constipation, decreased appetite, anemia, neutropenia, diarrhea, leukopenia, cough and thrombocytopenia.

For patients with recurrent or metastatic HER2 positive breast cancer, NCCN prefers a first-line treatment regimen of trastuzumab (Herceptin or biosimilars) and pertuzumab (Perjeta) along with a taxane. For patients who progress on first-line treatment, NCCN continues to recommend HER2 directed therapy which includes other treatment regimens containing trastuzumab, single-agent treatment with ado-trastuzumab (Kadcyla), or single agent treatment with Enhertu. They do not appear to prefer one agent over another for second-line treatment, but their recommendations for Enhertu are consistent with the FDA approved indication for patients who have received two or more prior anti-HER2-based regimens in the metastatic setting.

Outcome: Enhertu is a medical benefit managed by GHP that should not be added to the GHP Family pharmacy formulary. The following prior authorization criteria should apply:

- Medical record documentation that prescription is 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-positive breast cancer AND
- Medical record documentation of two or more prior anti-HER2 based therapies in the metastatic setting

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

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

Padcev (enfortumab vedotin-ejfv)

Review: Padcev is an antibody-drug conjugate consisting of human IgG1-kappa antibody, anti-Nectin-4, attached to a microtubule disrupting agent, monomethyl auristatin E (MMAE), by a cleavable maleimidocaproyl valine-citrulline linker. The antibody-drug conjugate binds Nectin-4, an adhesion protein found on the cell surface which is overexpressed in many cancer cells. This complex is then internalized and MMAE is cleaved from the complex resulting in microtubule disruption and leading to cell cycle arrest and cell death. NCCN recommends Padcev as a

preferred subsequent-line regimen for patients who have failed the preferred first- (platinum-based chemotherapy) and second-line (PD-L1 or PD-1 inhibitors) treatment options.

The efficacy of Padcev is demonstrated in Cohort 1 of EV-201, a Phase II, single-arm, open-label trial in 125 adult patients with locally advanced or metastatic urothelial carcinoma previously treated with both platinum chemotherapy and an anti-PD-1/L1 therapy. Patients included had progressed on their most recent therapy and had an ECOG performance status of < 1 and adequate organ function. Patients with motor or sensory neuropathy, CNS metastases, and uncontrolled diabetes were excluded. Patients received treatment with Padcev 1.25 mg/kg (maximum dose of 125 mg) by IV infusion on days 1, 8, and 15 of 28 day cycles until disease progression or unacceptable toxicity. The primary efficacy endpoint assessing confirmed objective response rate showed that 44% of patients had achieved a response with 12% achieving a full response and 32% achieving a partial response. The median duration of response was 7.6 months, which ranged from 3.6 to 11.3 months in patients who had achieved a complete response. Secondary endpoints showed 5.8 months for progression free survival and 11.7 months for overall survival.

Padcev includes warnings and precautions for hyperglycemia (in patients with or without existing diabetes), peripheral neuropathy, ocular disorders, and skin or skin and soft tissue reactions. During clinical trials, serious adverse reactions occurred in 46% of patients, most commonly urinary tract infection, cellulitis, febrile neutropenia, diarrhea, sepsis, acute kidney injury, dyspnea, and rash. Fatal adverse reactions resulting from acute respiratory failure, aspiration pneumonia, cardiac disorder, and sepsis occurred in 3.4% of patients. The most common adverse event leading to discontinuation was peripheral neuropathy and the most common adverse events leading to dose interruption were peripheral neuropathy, rash, and fatigue. Other adverse events that commonly occurred were altered taste, dry eye, pruritis, and dry skin.

For patients with metastatic bladder cancer, the standard of care is platinum-based chemotherapy resulting in an estimated overall survival of 9 to 15 months. For patients who relapse or don't respond to initial therapy, the median survival is reduced to 5 to 7 months. NCCN recommends PD-L1 or PD-1 inhibitors for second line treatment after platinum based therapy as these have been shown to extend overall survival. For subsequent-line therapy, NCCN recommends Padcev or Balversa as preferred treatment options. Although Balversa has shown efficacy in this population, it is limited to patients whose tumors have susceptible FGFR3 or FGFR2 genetic alterations.

Outcome: Padcev is a medical benefit that will be managed by GHP and should not be added the GHP Family pharmacy formulary. The following prior authorization criteria should apply:

- Medical record documentation that prescription is written by a hematologist or oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of locally advanced or metastatic urothelial cancer AND
- Medical record documentation that member has received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

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

FAST FACTS

Keytruda (pembrolizumab)

Updated Indication: Keytruda is now indicated for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.

Previously in urothelial carcinoma, Keytruda was indicated in patients with PD-L1 CPS $\geq$ 10 tumors or in patients who have progressed on or after platinum-containing chemotherapy or are not eligible for platinum-containing chemotherapy.

Current formulary status: Medical Benefit requiring prior authorization

Recommendation: No changes are recommended to the formulary placement of Keytruda at this time. It is recommended that the Keytruda policy criteria are updated to include the new indication (added criteria below):

- Patient has high-risk, non-muscle invasive bladder cancer (NMIBC)** **AND**
- Patient's disease is unresponsive to an adequate trial of Bacillus Calmette-Guerin (BCG) therapy** **AND**
- Patient is ineligible for or has elected not to undergo cystectomy

****Note:**

- BCG-unresponsive high-risk NMIBC is defined as persistent disease despite adequate BCG therapy, disease recurrence after an initial tumor-free state following adequate BCG therapy, or T1 disease following a single induction course of BCG.
- Adequate BCG therapy was defined as administration of at least five of six doses of an initial induction course plus either of: at least two of three doses of maintenance therapy or at least two of six doses of a second induction course.

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

Baxdela (delafloxacin) IV

Updated Indication: Baxdela is indicated in adults for the treatment of community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin susceptible [MSSA] isolates only), *Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila,* and *Mycoplasma pneumoniae.*

Previously Baxdela was indicated for the treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI) caused by designated susceptible bacteria.

Current formulary status: Medical Benefit requiring a prior authorization

Recommendation: No changes are recommended to the formulary placement. The prior authorization criteria should be updated to the following to account for the new indication:

- Medical record documentation that patient is greater than or equal to 18 years of age AND
- Medical record documentation of one of the following:
    - Documentation of a diagnosis of acute bacterial skin and skin structure infections (ABSSSI)* caused by susceptible isolates of the following: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group* (including S*treptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus*), *Streptococcus pyogenes*, *Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae*, or *Pseudomonas aeruginosa* **OR**
    - Documentation of community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin susceptible [MSSA] isolates only)*, Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae*, *Chlamydia pneumoniae*, *Legionella pneumophila,* and *Mycoplasma pneumoniae*

AND

- Prescription written by or in consultation with Infectious Disease AND
- If Baxdela was initiated during an inpatient stay, medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments OR a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity AND
- Medical record documentation of therapeutic failure on, intolerance to, contraindication to Baxdela tablets.

AUTHORIZATION DURATION:
If approved for ABSSSI, Baxdela IV will be authorized for 14 days, with a maximum of 28 doses.
If approved for CABP, Baxdela IV will be authorized for 10 days, with a maximum of 20 doses.

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

Discussion: No comments or questions.

Outcome: Keith Hunsicker made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed.

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

MEDICAL BENEFIT POLICY UPDATE

The following policy updates were made to the following Medical Benefit Policies based on recommendations from the Department of Human Services (DHS) during policy review submissions. The recommended policy changes

were suggested and/or required for further policy approval from DHS. These recommendations were made based on current treatment guidelines for each indication.

MBP 4.0 Intravenous Immune Globulin (IVIG)

- **Post-transfusion purpura**

  The following criteria must be met:

1. Medical record documentation of an onset of severe thrombocytopenia (platelet count less than 30,000/mm3) occurring 2-14 days post blood product transfusion.
2. ~~Medical documentation of failure, intolerance, or contraindication to corticosteroids and plasmapheresis;~~ ~~**OR**~~
3. ~~Platelet count less than 10,000/mm^3 with bleeding~~

- **Kawasaki Disease**

  The following criteria must be met:
  1. Documentation of a diagnosis of Kawasaki disease.
  2. Treatment with IVIG is begun within 10 days of the onset of fever. OR
  3. Patient has a delayed diagnosis (i.e., later than day 10 of fever) with ongoing systemic inflammation as manifested by elevation of ESR or CRP (CRP>3.0mg/dL) together with either persistent fever without other explanation or coronary artery aneurysms.

- **Myasthenia Gravis (Acute use)**

  The following criteria must be met:
  1. Must be prescribed by a neurologist; AND
  2. ~~Documentation of therapeutic failure on, intolerance to, or contraindication to at least two standard treatments (e.g. cholinesterase inhibitors, azathioprine, corticosteroids) and /or a combination of these treatments for a minimum of 3 months; AND~~

  Medical documentation of one of the following indications:
  3. Diagnosis of acute myasthenic crisis with decompensation; OR
  4. Use during postoperative period following a thymectomy; OR
  5. Use prior to planned thymectomy OR
  6. For short term bridge therapy (one-course of treatment) in patients with acute worsening symptoms with plans to start other immunosupressive treatments or corticosteroids.

*IVIG for any of the above acute indications will be approved for one course of treatment. One course of treatment will be limited to 5 days of IVIG therapy.

- **Chronic Inflammatory Demyelinating Polyneuropathy**

  All of the following criteria must be met:
1. Must be prescribed by a neurologist; AND
2. Documented evidence of focal or symmetric neurologic deficits that are slowly progressive or relapsing over 2 months ~~12 weeks~~ or longer AND
3. Physician provided documentation of EMG abnormalities consistent with the diagnosis of Chronic Inflammatory Demyelinating Polyneuropathy with the presence of at least ONE of the following: ~~(a minimum of 3 of the following must be documented):~~
   a. Motor distal latency prolongation ≥ 50% above ULN in two nerves (excluding median neuropathy at the wrist from carpal tunnel syndrome), OR
   b. Reduction of motor conduction velocity ≥ 30% below LLN in two nerves, OR

c. Prolongation of F-wave latency ≥ 30% above ULN in two nerves (≥ 50% if amplitude of distal negative peak CMAP <80% of LLN values), OR
d. Absence of F-waves in two nerves if these nerves have distal negative peak CMAP amplitudes ≥ 20% of LLN + ≥ 1 other demyelinating parameter in ≥ 1 other nerve, OR
e. Partial motor conduction block: ≥ 50% amplitude reduction of the proximal negative peak CMAP relative to distal, if distal negative peak CMAP ≥ 20% of LLN, in two nerves, or in one nerve + ≥1 other demyelinating parameter in ≥ 1 other nerve, OR
f. Abnormal temporal dispersion (>30% duration increase between the proximal and distal negative peak CMAP) in ≥ 2 nerves, OR
g. Distal CMAP duration (interval between onset of the first negative peak and return to baseline of the last negative peak) increase in ≥ 1 nerve (median ≥ 6.6 ms, ulnar ≥ 6.7 ms, peroneal ≥ 7.6 ms, tibial ≥ 8.8 ms) + ≥ 1 other demyelinating parameter in ≥ 1 other nerve
~~h. Partial conduction block of one or more motor nerves~~
~~i. Decreased conduction velocity of two or more motor nerves~~
~~j. Prolongation of distal latency of two or more motor nerves~~
~~k. Prolongation or absence of F-wave latencies in two or more motor nerves~~

Improvement should be apparent after 3 months ~~8 weeks~~ of treatment; otherwise, requests for further treatment will require Medical Director review.

~~Relapses may require periodic isolated treatments with a single dose of IVIG.~~

- **Multifocal Motor Neuropathy**

The following criteria must be met:

1. Must be prescribed by a neurologist; AND
2. Medical documentation of progressive symptoms for a minimum of 1 month ~~2 months~~; AND
3. Asymmetric limb weakness in at least two nerves AND
4. No objective sensory abnormalities except for minor vibration sense abnormalities in the lower limb AND
5. Documentation of a diagnosis of multifocal motor neuropathy with conduction block as shown on electrophysiologic study as evidenced by:
   - Definite Conduction block on a single nerve
     OR
   - Probable Conduction block in at least two nerves
     OR
   - Probable Conduction block in at least one nerve AND at least two (2) of the following:
     i. Elevated IgM anti-ganglioside GM1 antibodies
     ii. Increased CSF protein
     iii. increased T2-signal intensity on MRI of brachial plexus with diffuse nerve swelling
     iv. Objective clinical improvement following IVIG treatment

   - ~~or probable conduction block in two or more nerves~~
   - ~~Normal sensory nerve conduction in upper limb segments and normal sensory nerve action potential (SNAP) amplitude~~

~~Treatment is limited to one course of therapy defined as 3 months if approved. Requests for further treatment will require Medical Director review.~~

- **Catastrophic Antiphospholipid Syndrome (CAPS)** (III/C)

  All of the following criteria must be met:

  1. Documentation of patient with antiphospholipid syndrome (APS) with multiorgan failure (evidence of involvement of three or more organs, systems, and/or tissues AND
  2. Development of manifestations simultaneously or in less than one week AND
  3. Confirmation by histopathology of small vessel occlusion in at least one organ or tissue AND
  4. Laboratory confirmation of the presence of antiphospholipid antibodies (lupus anticoagulant, anticardiolipin antibodies, and/or anti-beta2-glycoprotein I antibodies)

     OR

     - All four criteria are met, except for only two organs, systems and/or sites of tissues involvement OR
     - All four criteria are met, except for laboratory confirmation OR
     - Criteria 1, 2, and 4 are met OR
     - Criteria 1,3, and 4 and the development of a third event in more than a week but less than a month, despite anticoagulation

  ~~5. Documentation of a life-threatening condition~~
  ~~6. Documentation of severe thrombocytopenia and microangiopathic hemolytic anemia~~
  ~~7. Documentation of failure on, contraindication to, or intolerance to conventional treatment with anticoagulation and steroids~~
  ~~8. Should be used in combination with plasma exchange~~

Geisinger Health Plan considers some conditions other than those listed under Indications to be **Experimental, Investigational or Unproven** and **NOT Medically Necessary**. These conditions include:

- Alzheimer's disease
- amyotrophic lateral sclerosis
- atopic dermatitis
- autism
- chronic fatigue syndrome
- chronic mucocutaneous candidiasis (CMCC)
- complex regional pain syndrome (CRPS)
- epilepsy
- inclusion body myositis
- Lyme disease
- neuromyelitis optica (NMO) (Devic's Disease)
- optic neuritis
- paraproteinemic demyelinating neuropathy (PDN)
- post-polio syndrome
- recurrent spontaneous miscarriage
- rheumatic fever
- secondary progressive multiple sclerosis (SPMS)
- ~~systemic lupus erythematosus~~

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on Tuesday, May 19th, 2020 at 1:00 HCN3A & 3B Conference room

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