P&T Committee Meeting Minutes
Medicaid
September 17, 2024

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	
Amir Antonius, Pharm.D.	Marika Bergenstock, DO (non-voting participant)
Emily Bednarz, Pharm.D.	Alyssa Cilia, RPh
Kristen Bender, Pharm.D.	Michael Evans, RPh
Jeremy Bennett, MD	Nichole Hossler, MD
Kim Castelnovo, RPh	Andrei Nemoianu, MD (non-voting participant)
Kimberly Clark, Pharm.D.	William Seavey, Pharm.D.
Bhargavi Degapudi, MD	Michael Shepherd, MD
Michael Dubartell, MD	
Kelly Faust, Pharm.D.	
Tricia Heitzman, Pharm.D.	
Jason Howay, Pharm.D.	
Keith Hunsicker, Pharm.D.	
Kelli Hunsicker, Pharm.D.	
Derek Hunt, Pharm.D.	
Emily Jacobson, Pharm.D.	
Dennis Janosczyk, Pharm.D.	
Alexandra Kempf-Malys	
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.	
Jonas Pearson, RPh	
Lauren Pheasant, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Melissa Sartori, Pharm.D.	
Kristen Scheib, Pharm.D.	
Leslie Shumlas, Pharm.D.	
Kirsten Smith, Pharm.D.	
Aubrielle Smith-Masri, Pharm.D.	
Michael Spishock, RPh	
Todd Sponenberg, Pharm.D.	
Jill Stone, Pharm.D.	
Luke Sullivan, DO	
Kevin Szczecina, RPh	
Amanda Taylor, MD	
Ariana Wendoloski, Pharm.D.	
Brandon Whiteash, Pharm.D.	

Margaret Whiteash, Pharm.D. Benjamin Andrick, Pharm.D. (non-voting participant) Birju Bhatt, MD (non-voting participant) Shelby Chan (pharmacy student) Alfred Denio, MD (non-voting participant) Jeremy Garris, Pharm.D. (non-voting participant) Macy Meng (pharmacy student)	

Call to Order: Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday September 17, 2024.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the July 16, 2024 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Tecelra (afamitresgene autoleucel)

Review: Tecelra is a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A02:03P, or -A02:06P positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices. This indication is approved under accelerated approval based on overall response rate and duration of response. Tecelra is the first FDA-approved T-cell receptor (TCR) gene therapy. It consists of CD4 and CD8 positive T cells transduced with a self-inactivating lentiviral vector (LV) expressing an affinity-enhanced T-cell receptor (TCR) specific for the human melanoma-associated antigen A4 (MAGE-A4), which is highly expressed in human leukocyte antigen (HLA)-A*02–positive synovial sarcoma and has restricted expression in normal tissues. Antigen-specific activation of Tecelra via TCR-peptide-HLA-A*02 complex results in T-cell proliferation, cytokine secretion, and killing of MAGE-A4/HLA-A*-2 expressing synovial sarcoma cells.

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

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

Outcome: Tecelra is a medical benefit and will require a prior authorization. The following prior authorization criteria should apply:

- Medical record documentation that Tecelra 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 unresectable or metastatic synovial sarcoma AND
- Medical record documentation of at least one (1) prior chemotherapy treatment AND
- Medical record documentation that member is HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, and HLA-A*02:06P allele–positive* AND
- Medical record documentation that the member has not had a prior allogeneic hematopoietic stem cell transplant AND
- Medical record documentation of tumor expression of melanoma-associated antigen A4 (MAGE-A4)

***Note:** Tecelra is contraindicated for patients who are heterozygous or homozygous for HLA-A*02:05P based on an alloreactivity screen which indicated in vitro alloreactivity against HLA-A*02:05**.**

Authorization Duration: One-time authorization for one administration of Tecelra.

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

Xolremdi (mavorixafor)

Review: Xolremdi is a selective CXC chemokine receptor 4 (CXCR4) antagonist indicated for patients 12 years of age and older with warts, hypogammaglobulinemia (deficiency in immunoglobulins), infections and myelokathexis (retention of neutrophils in the bone marrow), or WHIM syndrome, to increase the number of circulating mature neutrophils and lymphocytes. The recommended dosing of Xolremdi is 400mg once daily for patients weighing more than 50kg and 300mg once daily for patients weighing less than or equal to 50kg. Xolremdi is available as 100mg capsules and should be given on an empty stomach after an overnight fast and at least 30 minutes before food. Xolremdi should be stored in its original container and refrigerated at 36°F to 46°F until expiration date. Xolremdi capsules should be swallowed whole and should not be opened, broken or chewed. If a dose of Xolremdi is missed, the next dose should be taken as scheduled.

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

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

Outcome: Xolremdi will be a pharmacy benefit and should be added to the GHP Family Formulary. The following prior authorization criteria should apply:

- Medical record documentation of a diagnosis of WHIM (warts, hypogammaglobulinemia, infections, and myelokathexis) syndrome **AND**
- Medical record documentation of symptoms and complications associated with WHIM syndrome **AND**
- Medical record documentation that member is 12 years of age or greater **AND**
- Medical Record documentation that Xolremdi is being prescribed by an immunologist or hematologist **AND**
- Medical record documentation of member's weight **AND**
- Medical record documentation of baseline absolute neutrophil count (ANC) and absolute lymphocyte count (ALC)

GPI Level: GPI-10
Authorization Duration Approval will be given for an **initial duration of six (6) months** or less if the reviewing provider feels it is medically appropriate. After the initial six (6) month approval, subsequent approvals will be for a **duration of twelve (12) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- Medical record documentation of sustained improvement in absolute neutrophil count (ANC) and absolute lymphocyte count (ALC) **OR**
- Medical record documentation of clinical rationale for continuation of treatment (e.g. other benefits such as a decrease in infections)

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

Winrevair (sotatercept)

Review: Winrevair is an activin signaling inhibitor indicated for the treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1) to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events. Winrevair improves the balance between pro-proliferative and anti-proliferative signaling to modulate vascular proliferation. In rat models, Winrevair reduced inflammation and inhibited proliferation of endothelial and smooth muscle cells in diseased vasculature. Winrevair offers a new mechanism of action compared to other treatment options for PAH. Current treatment guidelines for patients with PAH recommend upfront dual therapy with an endothelin receptor antagonist (ERA) and phosphodiesterase-5 inhibitor (PDE5i) in patients with a low- or intermediate risk status and triple therapy (one drug targeting each vasodilatory pathway) for patients with high mortality risk.

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

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

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

- Medical record documentation that Winrevair is prescribed by a cardiologist or pulmonologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of World Health Organization (WHO) Group 1 pulmonary arterial hypertension AND
- Medical record documentation of World Health Organization (WHO) functional class II or III symptoms **AND**
- Medical record documentation of a baseline 6-minute walking distance **AND**
- Medical record documentation of therapeutic failure, intolerance to, or contraindication to one (1) formulary endothelin receptor antagonist (ERA) in combination with one (1) formulary phosphodiesterase-5 inhibitor (PDE5i) or one (1) soluble guanylate cyclase (sGC) stimulator

AUTHORIZATION DURATION: Initial authorization will be for 6 months. Subsequent authorizations will be for 6 months and will require:

- Medical record documentation of a 6-minute walking distance improved from baseline

GPI Level: GPI-12

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

Alyglo (immune globulin intravenous, human-stwk)

Review: Alyglo (immune globulin intravenous, human-stwk) is a 10% immune globulin liquid for intravenous injection indicated for the treatment of primary humoral immunodeficiency (PI.) Alyglo supplies a broad spectrum of neutralizing IgG antibodies to bacterial and viral pathogens, and their toxins. The mechanism of action has not been fully elucidated in PI. GC Biopharma reports that Alyglo is manufactured using a novel Cation Exchange Chromatography (CEX) process to remove coagulation factor XIa (FXIa) to undetectable levels. FXIa is potentially a cause of small numbers of thromboembolic events in patients receiving immunoglobulin infusions. However,

Alyglo prescribing information retains the class warning that thrombosis may occur with immune globulin intravenous (IGIV) products, including Alyglo.

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

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

Outcome: Alyglo is a medical benefit that will be GHP managed. Alyglo should not be added to the GHP Family pharmacy formulary. Alyglo should be added to the Medical Benefit Policy 4.0.

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

Voydeya (danicopan)

Review: Voydeya is a complement factor D inhibitor indicated as add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH). Voydeya has not been shown to be effective as monotherapy and should only be prescribed as add-on to ravulizumab or eculizumab. Voydeya is the second oral treatment option for patients with PNH. Voydeya reversibly binds complement Factor D and selectively inhibits the alternative complement pathway. In PNH, it acts proximally in the alternative pathway of the complement cascade to control preferentially C3 fragment-mediated EVH when co-administered with ravulizumab or eculizumab to maintain control over MAC-mediated IVH.

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

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

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

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) AND
- Medical record documentation that Voydeya is prescribed by a hematologist **AND**
- Medical record documentation that member has received vaccinations against encapsulated bacteria, including *Streptococcus pneumoniae and Neisseria meningitidis* **AND**
- Medical record documentation that member continues to experience clinically significant extravascular hemolysis (EVH)* despite at least 6 months of treatment with eculizumab or ravulizumab AND
- Medical record documentation that member will continue eculizumab or ravulizumab treatment in combination with Voydeya

***Note:** In clinical trials, clinically significant EVH was defined as anemia (hemoglobin [Hgb] $\leq$ 9.5 g/dL) with absolute reticulocyte count $\geq 120 \times 10^9$/L with or without transfusion support.

Authorization Duration: Initial approval will be for 6 months. Subsequent authorizations will be for 6 months and will require:

- Medical record documentation that member continues to receive Voydeya in combination with ravulizumab or eculizumab AND

- Medical record documentation of improvement of symptoms of extravascular hemolysis (EVH)*, including but not limited to increased hemoglobin levels, reduction in transfusions, improvement in hemolysis, decreases in LDH, and increased reticulocyte count.

GPI Level: GPI-12

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

Varzig (varicella zoster immune globulin [human]))

Review: Varizig was approved in December 2012 and is a varicella zoster immune globulin (human) indicated for post-exposure prophylaxis of varicella in high-risk individuals. High-risk groups include:

- Immunocompromised children and adults
- Newborns of mothers with varicella shortly before or after delivery
- Premature infants
- Neonates and infants less than one year of age
- Adults without evidence of immunity
- Pregnant women

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

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

Outcome: Varzig will be a medical benefit managed by GHP. No prior authorization criteria will apply

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

Formulary Alternatives: per Statewide PDL

Quantity Limits: 30-day supply per fill

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 the following:

- Medical record documentation of clinical improvement based on signs and symptoms of seborrheic dermatitis

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

August ELECTRONIC VOTE
An electronic vote was held from August 13, 2024, to August 19, 2024. Responses were received from 30 members (out of 53 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.

Blincyto

Updated Indication: Blincyto is now also indicated for the treatment of adult and pediatric patients one month and older with:

- CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%, and
- Relapsed or refractory CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL), and
- CD19-positive Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia (ALL) in the consolidation phase of multiphase chemotherapy

Recommendation: Blincyto is a medical benefit requiring prior authorization that is GHP managed. It is recommended to update the following criteria and auth durations as a result of the new indication.

Consolidation Phase B-cell Precursor ALL

- Prescription written by an oncologist/hematologist **AND**
- Medical record documentation of a diagnosis of CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) **AND**
- Medical record documentation of Philadelphia chromosome-negative disease **AND**
- Medical record documentation member is in the consolidation phase of multiphase chemotherapy

AUTHORIZATION DURATION:
For Adults: Approval will be limited to one lifetime 4 cycle (10 month) course. Subsequent approval for treatment past the 4 cycles of Blincyto will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.

For Pediatrics: Approval will be limited to one lifetime 1 cycle (1 month) course. Subsequent approval for treatment past the 1 cycle of Blincyto will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.

Note: For Consolidation Phase, in clinical trial E1910, patients received 2 cycles of Blincyto followed by 3 cycles of consolidation chemotherapy, then a third cycle of Blincyto followed by the fourth cycle of chemotherapy and a fourth cycle of Blincyto (total 8 cycles). In clinical trial 20120215, patients received Blincyto as the third cycle of consolidation, and then were to proceed to HSCT after this cycle.

GPI Level: GPI-12

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

Epkinly

Updated Indication: Epkinly is now indicated for adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. This indication is approved through accelerated approval based on response rate and durability of response.

Recommendation: Make the following update to the Epkinly policy:
Follicular Lymphoma

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Epkinly is written by a hematologist or oncologist AND
- Medical record documentation of a diagnosis of relapsed or refractory follicular lymphoma (FL) AND
- Medical record documentation of prior therapy with at least two lines of systemic therapy

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

Imfinzi

Updated Indication: Imfinzi is now indicated in combination with carboplatin and paclitaxel followed by Imfinzi as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR).

Recommendation: Make the following update to the Imfinzy policy:
Endometrial Cancer

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Imfinzi is prescribed by an oncologist or hematologist AND
- Medical record documentation of a diagnosis of primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR) AND
- Medical record documentation that Imfinzi will be used in combination with carboplatin and paclitaxel for 6 cycles, followed by continuation of Imfinzi as a single agent

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

Keytruda

Updated Indication: Keytruda is now indicated in combination with carboplatin and paclitaxel, followed by Keytruda as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma.

Recommendation: It is recommended that the following update be made to the Keytruda policy:
14. Endometrial Carcinoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of a diagnosis of primary advanced or recurrent endometrial carcinoma **AND**
    - Medical record documentation that Keytruda will be used in combination with carboplatin and paclitaxel followed by Keytruda as a single agent

OR

- Medical record documentation of a diagnosis of advanced endometrial carcinoma **AND**
- Medical record documentation of disease progression following at least one prior systemic therapy **AND**
- Medical record documentation that patient is not a candidate for curative surgery or radiation **AND**
- Medical record documentation of one of the following:
    - Medical record documentation that tumors are **not** microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) **AND**
    - Medical record documentation that Keytruda will be given in combination with lenvatinib (Lenvima)

OR

    - Medical record documentation that Keytruda will be used as a single agent for treatment of tumors that are microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

For all other indications:

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.

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

Opdivo

Updated Indication: Opdivo is now indicated for adult patients with unresectable or metastatic urothelial carcinoma, as first-line treatment in combination with cisplatin and gemcitabine.

Recommendation: Make the following update to the Opdivo policy:
MBP 126.0

6. *Urothelial Carcinoma*

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient ≥ 18 years of age **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma **AND**
    - Medical record documentation that Opdivo is NOT being used in combination with any other agent **AND**
    - One of the following:
        - Disease progression during or following platinum-containing chemotherapy **OR**
        - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

OR

- Medical record documentation of a diagnosis of unresectable or metastatic urothelial carcinoma **AND**
- Medical record documentation that Opdivo is being used as first-line treatment **AND**
- Medical record documentation that Opdivo is being used in combination with cisplatin and gemcitabine for up to six (6) cycles, after which it will be administered as a single agent.

OR

- Medical record documentation that Opdivo is being used in the adjuvant setting for a diagnosis of urothelial carcinoma **AND**
- Medical record documentation that Opdivo is NOT being used in combination with any other agent **AND**
- Both of the following:
  - Medical record documentation of radial resection of urothelial carcinoma **AND**
  - Medical record documentation of high risk of recurrence of urothelial carcinoma*

AND

- ~~Medical record documentation that Opdivo is NOT being used in combination with any other agent~~

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

Ultomiris

Updated Indication: Ultomiris is the first and only long-acting C5 complement inhibitor approved for the treatment of adult patients with anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD).

Recommendation: Make the following update to the Utlomiris policy:

1. Neuromyelitis Optica Spectrum Disorder (NMOSD)
   - Prescribed by or in consultation with a neurologist
   - Medical record documentation that member is 18 years or older AND
   - Medical record documentation of diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) AND
   - Medical record documentation that member is anti-Aquaporin-4 (AQP4) antibody positive AND
   - Medical record documentation of failure on intolerance to, or contraindication to rituximab or rituximab biosimilar AND
   - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Enspryng AND
   - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to eculizumab or biosimilar.

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

Wainua Update

Recommendation: During the review of the GHP Family Wainua policy DHS requested we update the renewal criteria to be as noted below. It is recommended the Committee approve the update.

Authorization Duration: 12 months. Subsequent approvals will be for an additional 12 months and will require medical record documentation of continued disease improvement, stabilization, slowing of disease progression, or improved quality of life.

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

Meeting adjourned at 3:08 pm

Future Scheduled Meetings
The next bi-monthly scheduled meeting will be held on November 19, 2024 at 1:00 p.m.

Meetings will be held virtually via phone/Microsoft Teams