

**P&T Committee Meeting Minutes**  
**Medicaid**  
**September 21, 2021**

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<b>Present (via Teams):</b> Bret Yarczower, MD, MBA – Chair Megan Ammon, Pharm.D. Kristen Bender, Pharm.D. Jeremy Bennett, MD Dean Christian, MD Alyssa Cilia, RPh Kimberly Clark, Pharm.D. Rajneel Farley, Pharm.D. Kelly Faust Pharm.D. Tricia Heitzman, Pharm.D. Jason Howay, Pharm.D. Keith Hunsicker, Pharm.D. Kelli Hunsicker, Pharm.D. Derek Hunt, Pharm.D. Jamie Miller, RPh Kimberly Reichard, Pharm.D. Melissa Renn, Pharm.D. Kristen Scheib, Pharm.D. William Seavey, Pharm.D. Michael Shepherd, MD Leslie Shumlas, Pharm.D. Aubrielle Smith Pharm.D. Michael Spishock, RPh Todd Sponenberg, Pharm.D. Jill Stone, Pharm.D. Robert Strony, MD MBA Kevin Szczecina, RPh Amanda Taylor, MD Brandon Whiteash, Pharm.D. Adam Root (non-voting participant)	<b>Absent:</b> Holly Bones, Pharm.D. Kim Castelnovo Michael Evans, RPh Nichole Hossler, MD Phillip Krebs, R.EEG T Perry Meadows, MD Austin Paisley, Pharm.D. Jonas Pearson, RPh Angela Scarantino Richard Silbert, MD
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**Call to Order:**

Dr. Bret Yarczower called the meeting to order at 1:03 p.m., Tuesday, September 21, 2021.

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**Review and Approval of Minutes, Reviews, Fast Facts, and Updates:** Dr. Bret Yarczower asked for a motion or approval to accept the June 20, 2021 minutes as written. Minutes approved unanimously. None were opposed.

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**DRUG REVIEWS**

**Artesunate (artesanate)**

**Review:** Artesunate, and its active metabolite DHA, inhibit protein and nucleic acid synthesis and lead to ultrastructural changes as well as decrease in parasite growth and survival. Both artesunate and DHA are active against the different asexual forms of *Plasmodium* parasites, including the chloroquine resistant strains, and clear

parasitemia within 48 to 72 hours. Artesunate and DHA are not active against the hypnozoite liver stage forms of *P. vivax* or *P. ovale* so concomitant therapy with an antimalarial agent such as an 8-aminoquinoline drug is necessary to prevent relapses of malaria. The CDC and WHO recommend that all patients with severe malaria, regardless of infecting species be treated with intravenous artesunate as soon as possible. Treatment with intravenous artesunate should continue for at least 24 hours after initiation of treatment before switching to an oral follow-up treatment once the patient is able to tolerate oral therapy. Artesunate has been available in the U.S. since 2007 through the FDA's Expanded Access program from the CDC under an investigational new drug (IND) protocol for treatment of severe malaria. Artesunate will continue to be available through the CDC IND protocol while Artesunate for Injection™ is launched and distributed. The efficacy of intravenous artesunate for the treatment of severe malaria was evaluated in a randomized, active-controlled trial in Asia (Trial 1) and a supportive published randomized active-controlled trial in Africa (Trial 2). Trial 1 was an international randomized, open-label, multicenter trial conducted in Bangladesh, India, Indonesia, and Myanmar in 1,461 hospitalized patients with severe malaria. Patients were randomized to intravenous treatment with either intravenous artesunate or intravenous quinine. Efficacy was based on in-hospital mortality rates which were significantly lower in the artesunate group (13%) compared to the quinine group (21%). Trial 2 was a randomized, open-label, multicenter trial comparing parenteral artesunate to parenteral quinine in pediatric patients (<15 years of age) with severe malaria in nine African countries. Dosing was similar to trial 1, except both artesunate and quinine could be administered either intravenously or intramuscularly (not an approved route of administration). Treatment with artesunate showed an improvement of in-hospital mortality rates over quinine with rates comparable to Trial 1. There are no black box warnings for Artesunate. Warnings and precautions include hypersensitivity, including anaphylaxis, and post-treatment hemolysis. Post-artesunate delayed hemolysis is characterized by decreased hemoglobin and laboratory evidence of hemolysis (decreased haptoglobin, increased lactate dehydrogenase) occurring at least 7 days after initiating artesunate treatment. Some reported cases were severe enough to require transfusion. Patients need to be monitored for 4 weeks following treatment for evidence of hemolytic anemia. During Trial 1, the most common adverse reactions were acute renal failure requiring dialysis, hemoglobinuria, and jaundice. During Trial 2, the safety profile was generally similar to that of Trial 1, but a greater incidence of neurological impairment at hospital discharge was observed in the artesunate group compared to the quinine arm.

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

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

**Outcome:** Artesunate will be covered as a medical benefit and should not be added to the GHP Family formulary. No prior authorization will be required

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

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### **Rylaze (asparaginase erwinia chrysanthemi (recombinant)- rywn)**

**Review:** Rylaze is an asparagine specific bacterial enzyme (L-asparaginase) produced by fermentation of genetically engineered *Pseudomonas fluorescens* bacterium containing the DNA which encodes for asparaginase *Erwinia chrysanthemi*. It catalyzes the conversion of L-asparagine to aspartic acid and ammonia, which leads to the killing of leukemic cells with the depletion of plasma asparagine. Leukemic cells with low expression of asparagine synthetase have a reduced ability to synthesize asparagine, and therefore depend on an exogenous source of asparagine for survival. Rylaze is a short-acting asparaginase product which offers an alternative to asparaginase products derived from *Escherichia coli* (*E. coli*), to which up to 30% of patients develop a hypersensitivity or

allergy. Study JZP458-201 is a single-arm, open-label, multi-cohort trial which evaluated the efficacy of Rylaze for the treatment of 102 patients with ALL or LBL who have developed hypersensitivity to *E.coli*-derived asparaginase as a component of a multi-agent chemotherapeutic regimen. A treatment course consisted of Rylaze at various doses administered intramuscularly every Monday, Wednesday, and Friday for a total of 6 doses to replace each dose of pegaspargase. Efficacy was based on demonstration of the achievement and maintenance of nadir serum asparaginase activity (NSAA) above the level of 0.1 U/mL. Results of modeling and simulations showed that for the recommended dosage of Rylaze 25 mg/m<sup>2</sup> IM every 48 hours, 93.6% of patients maintained NSAA ≥ 0.1 U/mL at 48 hours after a dose. There is no black box warning for Rylaze but there are warnings and precautions for hypersensitivity, pancreatitis, thrombosis, hemorrhage and hepatotoxicity. During clinical trials, there was one fatal adverse reaction (infection), and serious adverse reactions were reported in 55% of patients treated with the recommended dosage of Rylaze. All patients treated with Rylaze developed neutropenia, anemia, or thrombocytopenia. The most common non-hematological adverse reactions in patients were abnormal liver test, nausea, musculoskeletal pain, fatigue, infection, headache, pyrexia, drug hypersensitivity, febrile neutropenia, decreased appetite, stomatitis, bleeding, and hyperglycemia

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

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

**Outcome:** Rylaze is a medical benefit and should not be added to the GHP Family pharmacy formulary. The following prior authorization criteria should apply:

- Medical record documentation that Rylaze is prescribed by a hematologist or oncologist AND
- Medical record documentation of age greater than or equal to 1 month AND
- Medical record documentation that Rylaze will be given as a component of a multi-agent chemotherapeutic regimen in patients with a diagnosis of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) AND
- Medical record documentation of a hypersensitivity to *E. coli*-derived asparaginase

**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.

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## FAST FACTS

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### Keytruda

**Updated Indication:** For adult patients with advanced renal cell carcinoma, the Keytruda dosage is 200 mg every 3 weeks or 400 mg every 6 weeks, administered in combination with Lenvatinib (20 mg once daily) until disease progression, unacceptable toxicity, or for Keytruda, up to 24 months.

For adult patients with high-risk early-stage TNBC, Keytruda is given in combination with chemotherapy for neoadjuvant treatment for 24 weeks (8 doses of 200 mg every 3 weeks or 4 doses of 400 mg every 6 weeks) or until disease progression or unacceptable toxicity. Neoadjuvant treatment is followed by adjuvant treatment with

Keytruda as a single agent for up to 27 weeks (9 doses of 200 mg every 3 weeks or 5 doses of 400 mg every 6 weeks) or until disease progression or unacceptable toxicity.

There is no change to the dose of Keytruda for adult patients with locally advanced or metastatic urothelial carcinoma. The dosage is 200 mg every 3 weeks for 400 mg every 6 weeks, until disease progression, unacceptable toxicity, or up to 24 months

**Recommendation:** There are no changes to the formulary placement of Keytruda. The following change is recommended to the criteria in the Medical Benefit Policy 119.0 to incorporate the new indications. The following changes are recommended to the authorization duration of Keytruda to incorporate the new TNBC indication which is indicated for a total of up to 24 weeks as neoadjuvant treatment followed by up to 27 weeks of adjuvant treatment. A previous change to the authorization duration for adjuvant treatment of metastatic melanoma (completely resected melanoma) was approved in May 2019 but was not updated in MBP 119.0. The following changes to the authorization duration in MBP 119.0 are recommended to reflect that change along with the new indication for TNBC

## Medical Benefit Policy 119.0

### 12. Renal Cell Carcinoma (RCC)

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient is  $\geq 18$  years of age AND
- Medical record documentation of a diagnosis of advanced renal cell carcinoma AND
- Medical record documentation that Keytruda is being used in combination with axitinib (Inlyta) OR lenvatinib (Lenvima) AND
- Medical record documentation that Keytruda in combination with axitinib (Inlyta) OR lenvatinib (Lenvima) are being used as first-line treatment for advanced disease

### 17. Triple Negative Breast Cancer

- Prescription written by a hematologist/oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of one of the following:
  - Medical record documentation of locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) AND both of the following:
    - Medical record documentation that tumors express PD-L1 [Combined Positive Score (CPS) greater than or equal to 10] as determined by an FDA approved test AND
    - Medical record documentation that Keytruda will be given in combination with chemotherapy (paclitaxel, paclitaxel protein-bound, or gemcitabine and carboplatin).

OR

- Medical record documentation of high-risk, early-stage triple-negative breast cancer (TNBC) AND
- Medical record documentation that Keytruda will be given in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery

### 6. Urothelial Carcinoma

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient is  $\geq 18$  years of age AND
- Medical record documentation of locally advanced or metastatic urothelial carcinoma AND
- Medical record documentation of 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**

- Patient is not eligible cisplatin-containing chemotherapy\* AND
- Tumors express PD-L1 (combined positive score [CPS] greater than or equal to 10) as determined by an FDA-approved test

**OR**

- Patient is not eligible for any platinum-containing chemotherapy (regardless of PD-L1 status)

**OR**

- 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:**

- In clinical trials, patients who were not considered cisplatin-eligible had the following characteristics: baseline creatinine clearance of <60 mL/min, ECOG performance status of 2, ECOG 2 and baseline creatinine clearance of <60 mL/min, other reasons (Class III heart failure, Grade 2 or greater peripheral neuropathy, and Grade 2 or greater hearing loss).

**AUTHORIZATION DURATION:** Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

**Recommended Authorization duration:**

**For adjuvant treatment of metastatic melanoma (completely resected melanoma) and neoadjuvant/adjuvant treatment of early-stage triple negative breast cancer:**

Initial approval will be for 6 months. One subsequent approval will be for an additional 6 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease. Authorization of Keytruda for the adjuvant treatment of metastatic melanoma should not exceed the FDA-approved treatment duration of 1 year (12 months). Authorization of Keytruda for the treatment of early-stage triple negative breast cancer should not exceed the approved treatment duration of 24 weeks for neoadjuvant therapy and 27 weeks for adjuvant therapy. 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 all other indications:**

Initial approval will be for 6 months. Subsequent approvals will be for 12 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

**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.

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## Darzalex Faspro

**Updated Indication:** Darzalex Faspro is now indicated for the treatment of adult patients with multiple myeloma in combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (PI).

**Recommendation:** There will be no changes to formulary status, authorization duration, or quantity limits at this time. However, it is recommended to make the following updates to the current policy.

- Prescription written by a hematologist/oncologist AND
- Medical record documentation a diagnosis of multiple myeloma AND

**If newly diagnosed multiple myeloma (transplant ineligible):**

- Medical record documentation that the member is not eligible for stem-cell transplantation (e.g. coexisting conditions, age greater than 65, etc.) AND
- Medical record documentation that Darzalex will be given in combination with one of the following options:
  - Bortezomib (Velcade), melphalan, AND prednisone [VMP] OR
  - Lenalidomide (Revlimid) AND dexamethasone

OR

**If newly diagnosed multiple myeloma (transplant eligible):**

- Medical record documentation that the member is eligible for stem-cell transplantation AND
- Medical record documentation that Darzalex will be given in combination with bortezomib (Velcade), thalidomide, and dexamethasone (DVTd)

OR

**If relapsed/refractory multiple myeloma:**

- One of the following:
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three prior lines of therapy including a proteasome inhibitor (including but not limited to Velcade\*, Kyprolis\*, or Ninlaro\*) and an immunomodulatory agent (including but not limited to Pomalyst\*, Revlimid\*, Thalomid\*) OR
  - Medical record documentation that the patient is double-refractory to a proteasome inhibitor (including but not limited to Velcade\*, Kyprolis\*, or Ninlaro\*) and an immunomodulatory agent (including but not limited to Pomalyst\*, Revlimid\*, Thalomid\*) OR
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior line of therapy including lenalidomide and a proteasome inhibitor (including but not limited to Velcade\*, Kyprolis\*, or Ninlaro\*) AND Darzalex will be prescribed in combination with pomalidomide and dexamethasone OR
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 1 prior therapy including a proteasome inhibitor (including but not limited to Velcade\*, Kyprolis\*, or Ninlaro\*) or an immunomodulatory agent (including but not limited to Pomalyst\*, Revlimid\*, Thalomid\*) AND one of the following:
    - Medical record documentation that Darzalex will be prescribed in combination with lenalidomide and dexamethasone OR
    - Medical record documentation that Darzalex will be prescribed in combination with bortezomib and dexamethasone OR
    - ~~Medical record documentation that Darzalex will be prescribed in combination with carfilzomib (Kyprolis) and dexamethasone~~

OR

If light-chain (AL) amyloidosis:

- Prescription written by or in consultation with and hematologist/oncologist AND
- Medical record documentation of a diagnosis of light-chain (AL) amyloidosis AND
- Medical Record documentation that the patient does NOT have New York Heart Association (NYHA) Class IIIB (as defined by slight limitation during daily living activity and comfortable at rest) or Class IV heart failure, or mayo cardiac stage IIIB\* AND
- Medical record documentation that Darzalex Faspro will be used in combination with bortezomib, cyclophosphamide and dexamethasone

#### Other Recommendations

##### **Darzalex**

Darzalex received approval for adult patients with multiple myeloma in combination with pomalidomide and dexamethasone in patients who received at least two prior therapies including lenalidomide and a proteasome inhibitor. This indication was approved June 16, 2017, however it was never presented for approval at P&T. It is recommended to update the current policies to include all of the FDA approved indications

There are no changes to formulary status or authorization duration at this time. However, it is recommended to update the criteria to include all the FDA-approved indications.

- Prescription written by a hematologist/oncologist AND
- Medical record documentation a diagnosis of multiple myeloma AND

##### If newly diagnosed multiple myeloma (transplant ineligible):

- Medical record documentation that the member is not eligible for stem-cell transplantation (e.g. coexisting conditions, age greater than 65, etc.) AND
- Medical record documentation that Darzalex will be given in combination with one of the following options:
  - Bortezomib (Velcade), melphalan, AND prednisone [VMP] OR
  - Lenalidomide (Revlimid) AND dexamethasone

OR

##### If newly diagnosed multiple myeloma (transplant eligible):

- Medical record documentation that the member is eligible for stem-cell transplantation AND
- Medical record documentation that Darzalex will be given in combination with bortezomib (Velcade), thalidomide, and dexamethasone (DVTd)

OR

##### If relapsed/refractory multiple myeloma:

- One of the following:
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three prior lines of therapy including a proteasome inhibitor (including but not limited to Velcade\*, Kyprolis\*, or Ninlaro\*) and an immunomodulatory agent (including but not limited to Pomalyst\*, Revlimid\*, Thalomid\*) OR
  - Medical record documentation that the patient is double-refractory to a proteasome inhibitor (including but not limited to Velcade\*, Kyprolis\*, or Ninlaro\*) and an immunomodulatory agent (including but not limited to Pomalyst\*, Revlimid\*, Thalomid\*) OR
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two prior lines of therapy including lenalidomide and a proteasome inhibitor (including but not limited to Velcade\*, Kyprolis\*, or Ninlaro\*) AND Darzalex will be prescribed in combination with pomalidomide and dexamethasone OR
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 1 prior therapy including a proteasome inhibitor (including but not limited to Velcade\*, Kyprolis\*, or Ninlaro\*) or an immunomodulatory agent (including but not limited to Pomalyst\*, Revlimid\*, Thalomid\*) AND one of the following:

- Medical record documentation that Darzalex will be prescribed in combination with lenalidomide and dexamethasone OR
- Medical record documentation that Darzalex will be prescribed in combination with bortezomib and dexamethasone OR
- Medical record documentation that Darzalex will be prescribed in combination with carfilzomib (Kyprolis) and dexamethasone

**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.

**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.

## **Jemperli**

**Updated Indication:** Jemperli is now indicated for treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options.

**Recommendation:** There are no changes recommended to the formulary placement or the authorization duration of Jemperli. It is recommended that the following prior authorization criteria be added to the Medical Benefit Policy for Jemperli.

### **Solid Tumors**

- Medical record documentation that Jemperli is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of recurrent or advanced solid tumors **AND**
- Medical record documentation of mismatch repair deficient (dMMR) as determined by an FDA approved test **AND**
- Medical record documentation of disease progression on or following at least one prior treatment **AND**
- Medical record documentation of no satisfactory alternative treatment options

**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.

## **Padcev**

**Updated Indication:** Padcev is now indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy..

**Recommendation:** There are no changes recommended to the formulary placement or authorization duration of Padcev. The following changes are recommended for Medical Benefit Policy 209.0.

- 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 of one of the following:**
  - 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 OR
  - **Medical record documentation that member has received at least one prior line of therapy and is ineligible for cisplatin-containing chemotherapy\***

**\*Note to reviewer:** In clinical trials, patients who were not considered cisplatin-eligible had one or more of the following characteristics: baseline creatinine clearance of 30 – 59 mL/min, ECOG performance status of 2, or Grade 2 or greater hearing loss.

**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.

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## Updates

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### Istodax

**Recommendation:** It is recommended that Medical Benefit Policy 078.0 be updated to reflect the removal of the PTCL indication.

**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.

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### Xiaflex

**Recommendation:** It is recommended to make the following changes to MBP 80.0.

**For treatment of Dupuytren contracture:**

- Medical record documentation of Dupuytren's contracture with a palpable cord AND
- Prescribed by a provider experienced in injection procedures of the hand and treating Dupuytren's contracture

**LIMITATIONS:**

Xiaflex® will be limited to a maximum of three (3) injections per cord

**For treatment of Peyronie's disease:**

- Medical record documentation of a diagnosis of moderate to severe Peyronie's Disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy **AND**

- ~~Medical record documentation that Xiaflex will be used in combination with (or therapeutic failure on, intolerance to, or contraindication to) pentoxifylline~~

**LIMITATIONS:**

Xiaflex® will be limited to a maximum of 8 total injection procedures (4 treatment cycles) per plaque.

**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.

**Tranexamic acid**

**Recommendation:** After review of treatment options for heavy menstrual bleeding and MAC pricing, it is recommended that the following prior authorization criteria and quantity limits apply for Medicaid for Tranexamic acid:

- Do not see medical record documentation of therapeutic failure on, intolerance to, or contraindication to one preferred contraceptive **AND** to either naproxen 250mg or 500mg tablets **OR** ibuprofen 200mg or 600mg tablets.
- Limit of 30 tablets per fill

**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.

The **September 2021 DUR Update** was presented to the Committee for review.

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

**August Electronic Vote**

Due to the volume of full drug reviews, fast facts, and updates that must reviewed by the P&T Committee an additional electronic vote was held from August 24, 2021 to August 27, 2021. Responses were received from 22 members (out of 39) and all voted to approve.

The following was approved for GHP Family:

<b>Drug</b>	<b>Recommendation</b>
Amondys 45	Medical drug requiring prior authorization: <ul style="list-style-type: none"> <li>• Medical record documentation of interdisciplinary team involvement including, at a minimum, neurology, cardiology, pulmonology, and a genetic specialist (e.g., geneticist, genetic counselor, etc.) <b>AND</b></li> <li>• Medical record documentation of Duchenne’s Muscular Dystrophy (DMD) confirmed by genetic testing <b>AND</b></li> </ul>

	<ul style="list-style-type: none"> <li>• Medical record documentation that the member has a confirmed mutation of the DMD gene that is amenable to exon 45 skipping confirmed by a genetic counselor <b>AND</b></li> <li>• Medical record documentation of a baseline evaluation, including a standardized assessment of motor function by a neurologist with experience treating Duchenne muscular dystrophy <b>AND</b></li> <li>• Medical record documentation that Amondys 45 is being given concurrently with oral corticosteroids unless contraindicated or intolerant <b>AND</b></li> <li>• Medical record documentation that patient will receive a dose consistent with the Food and Drug Administration (FDA) approved labeling (maximum dose of 30 mg/kg infused once weekly)</li> </ul> <p><b>Authorization duration:</b> 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 the following:</p> <ul style="list-style-type: none"> <li>• Medical record documentation that the member continues to benefit from treatment with casimersen <b>AND</b></li> <li>• Medical record documentation of an annual evaluation, including an assessment of motor function ability, by a neurologist with experience treating Duchenne muscular dystrophy <b>AND</b></li> <li>• Medical record documentation that Amondys 45 continues to be given concurrently with oral corticosteroids unless contraindicated or intolerant <b>AND</b></li> <li>• Medical record documentation that the patient will continue to receive a dose consistent with the Food and Drug Administration (FDA) approved labeling (maximum dose of 30 mg/kg infused once weekly)</li> </ul>
Evkeeza	<p>Medical drug requiring prior authorization:</p> <ul style="list-style-type: none"> <li>• Medical record documentation of a diagnosis of homozygous familial hypercholesterolemia that is caused by mutations of the low-density lipoprotein (LDL) receptor (LDLr) gene <b>AND</b></li> <li>• Medical record documentation that Evkeeza is prescribed by a lipidologist or cardiologist <b>AND</b></li> <li>• Medical record documentation of age greater than or equal to 12 years <b>AND</b></li> <li>• Medical record documentation of failure to adequately control low-density lipoprotein (LDL) levels with combination of maximum tolerated statin dose and low-density lipoprotein (LDL) apheresis treatment defined as: <ul style="list-style-type: none"> <li>o Greater than or equal to 130 mg/dL in pediatric patients greater than or equal to 12 years of age and less than 18 years of age <b>OR</b></li> <li>o Greater than or equal to 100 mg/dL in adult patients without cardiovascular disease <b>OR</b></li> <li>o Greater than or equal to 70 mg/dL in adult patients with established cardiovascular disease</li> </ul> </li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Medical record documentation of Evkeeza to be used in adjunct with maximum tolerated statin dose <b>AND</b> low-density lipoprotein (LDL) apheresis <b>AND</b></li> <li>• Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one formulary proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor.</li> </ul>

	<b>AUTHORIZATION DURATION:</b> Initial authorization will be for a period of six (6) months. After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year, requiring medical record documentation that current medical necessity criteria are met and that therapy has been effective
REGEN-COV	Medical benefit
Shingrix	It is recommended that the Age limit be updated to 19 to 99 years to incorporate the new indication.

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

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Meeting adjourned at 3:49 pm

**Future Scheduled Meetings**

The next bi-monthly scheduled meeting will be held on Tuesday, November 16, 2021 at 1:00 via Microsoft Teams.