P&T Committee Meeting Minutes
Commercial/Marketplace/GHP Kids
February 28, 2022 e-vote

CLASS REVIEW

COVID 19 New Drug Reviews and Updates

Review: On February 4, 2020, the HHS Secretary determined that COVID-19 was a public health emergency with significant potential to affect national security or the health and security of U.S. citizens living abroad. An Emergency Use Authorization (EUA) is an FDA authorization for the emergency use of an unapproved product or unapproved use of an approved product during a public health emergency. Criteria for issuing an EUA include:

- The biological agent(s) can cause a serious or life-threatening disease or condition;
- Based on the totality of the available scientific evidence (including data from adequate and well controlled clinical trials, if available), it is reasonable to believe that:
    - The product may be effective in diagnosing, treating, or preventing the serious or life threatening disease or condition; and
    - The known and potential benefits of the product – when used to diagnose, prevent, or treat such disease or condition – outweigh the known and potential risks of the product, taking into consideration the material threat posed by the biological agent(s);
- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the serious or life-threatening disease or condition.

A current list of the medications with an EUA can be found on the FDA website at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization. The FDA will continue to closely monitor the variants and will determine whether use in a geographic region of the U.S. which is consistent with the scope of the EUA. EUAs for medications may be revoked or limited based on clinical data. SARS-CoV-2 variant frequency data for states and jurisdictions can be assessed on the CDC website.

Patients with symptomatic COVID-19 infections can experience a wide range of clinical manifestations but may progress to pneumonia, respiratory failure, multi-organ failure, and death. Severe and critical illness in patients is defined as worsening pulmonary status requiring hospitalization, supplemental oxygen, non-invasive ventilation, high-flow oxygen devices, invasive mechanical ventilation, or ECMO. Medical conditions which place patient at a higher risk of progression to severe COVID-19 can include:

- Older age
- Obesity or being overweight
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease or hypertension
- Chronic lung diseases
- Sickle cell disease
- Neurodevelopmental disorders or other conditions that confer medical complexity
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)

EUAs and FDA Approved Indications[1-15]:

Trade Name/ Manufacturer/ Benefit Type	Generic Name	Mechanism of Action	EUA/FDA Approved Indication
Emergency Use Authorizations			
Sotrovimab *GlaxoSmithKline* Medical Benefit		Monoclonal antibody	• For the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing and who are at a high-risk of progression to severe COVID-19, including hospitalization or death <u>Limitations:</u> Sotrovimab is not authorizaed for use in patients: - Who are hospitalized due to COVID-19 OR - Who require oxygen therapy due to COVID-19 OR - Who require an increase in baseline oxygen flow rate due to COVID-19 (in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity)

Bebtelovimab
 	
Eli Lilly and Company
 	
Medical Benefit
		Monoclonal antibody	• For the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg):
			  • with positive results of direct SARS-CoV-2 viral testing, and
			  • who are at high risk for progression to severe COVID-19, including hospitalization or death, and
			  • for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.
			<u>Limitations:</u>
			- Bebtelovimab is not authorized for treatment of mild-to-moderate COVID-19 in geographic regions where infection is likely to have been caused by a non-susceptible SARS-CoV-2 variant based on available information including variant susceptibility to this drug and regional variant frequency.
			  o FDA's determination and any updates will be available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs.
			- Bebtelovimab is not authorized for use in patients, who:
			  o are hospitalized due to COVID-19, OR
			  o require oxygen therapy and/or respiratory support due to COVID-19, OR
			  o require an increase in baseline oxygen flow rate and/or respiratory support due to COVID-19 and are on chronic oxygen therapy and/or respiratory support due to underlying non-COVID-19 related comorbidity.

Paxlovid *Pfizer Inc.* Pharmacy Benefit	nirmatrelvir co-packaged with ritonavir	Nirmatrelvir – SARS-CoV-2 main protease (Mpro) inhibitor Ritonavir – HIV-1 protease inhibitor and CYP3A inhibitor (inhibits metabolism of nirmaltrelvir)	• For the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing and who are at a high-risk of progression to severe COVID-19, including hospitalization or death <u>Limitations:</u> - Paxlovid is not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19 - Paxlovid is not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19 - Paxolovid is not authorized for use for longer than 5 days
Molnupiravir *Merck & Co., Inc.* Pharmacy Benefit		Prodrug with antiviral activity metabolized to cytidine nucleoside analogue (NHC)	• For the treatment of mild to moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing and who are at a high-risk of progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate. <u>Limitations:</u> Molnupiravir is not authorized: - For use in patients less than 18 years of age - For initiation of treatment in patients requiring hospitalization due to COVID-19. Benefit of treatment has not been observed in subjects when treatment was initiation after hospitalization due to COVID-19 - For use for longer than 5 consecutive days - For pre-expsoure or post-exposure prophylaxis for prevention of COVID-19
Evusheld *AstraZeneca Pharmaceuticals LP* Medical Benefit	tixagevimab co-packaged with cilgavimab	SARS-CoV-2 spike protein-directed attachment inhibitor	• For pre-exposure prophylaxis of COVID-19 in adults and pediatric patients (12 years and older weighing at least 40 kg) • Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **AND** • Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatements AND may not mount an adequate immune response to COVID-19 vaccine **OR** • For whom vaccination with any available COVID-19 vaccine according to the approved or authorized schedule is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s). <u>Limitations:</u> Evusheld is not authorized for use in individuals: - For treatment of COVID-19 OR - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2

Full FDA Approval			
Comirnaty *Pfizer, Inc.* Medical or Pharmacy Benefit (All LOB)	COVID-19 Vaccine, mRNA	mRNA vaccine for SARS-CoV-2	• For active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.
Spikevax *Moderna US, Inc.* Medical or Pharmacy Benefit (All LOB)	COVID-19 Vaccine, mRNA	mRNA vaccine for SARS-CoV-2	• For active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older

FDA Authorization Change			
REGEN-COV *Regeneron Pharmaceuticals, Inc.* Medical Benefit	Casirivimab/ imdevimab	Monoclonal antibody	**Due to the high frequency of the Omicron variant, REGEN-COV is <u>not</u> currently authorized in any U.S. region. Therefore, REGEN-COV may not be administered for treatment or post-exposure prevention of COVID-19 under the Emergency Use Authorization until further notice by the Agency.**
Bamlanivimab/etesevimab *Eli Lilly and Company* Medical Benefit		Monoclonal antibody	**Due to the high frequency of the Omicron variant, bamlanivimab and etesevimab are <u>not</u> currently authorized in any U.S. region. Therefore, these drugs may not be administered for treatment or post-exposure prevention of COVID-19 under the Emergency Use Authorization until further notice by the Agency.**

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

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

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

Outcome:
Sotrovimab, Bebtelovimab, and Evusheld will be covered as medical benefits and will not be added to the Commercial, Marketplace, and GHP Kids pharmacy formularies. Sotrovimab, Bebtelovimab, and Evusheld will not require a prior authorization.

Paxlovid and Molnupiravir are pharmacy benefits. They will be free to patients who qualify under the Emergency Use Authorization parameters issued by the FDA. They will be added to the formulary to cover the cost of administration only at this time.

Comirnaty and Spikevax will be covered as medical or pharmacy benefits and will not require a prior authorization. They will be covered as a preventive vaccine for a $0 copay.

The emergency use authorization for Actemra IV for the treatment of COVID-19 is currently only indicated in hospitalized patients and only applicable to the intravenous formulation. It will be limited to inpatient use only and is not covered for outpatient use at this time. It is recommended that the following note to the reviewer be added to the Medical Benefit Policy 76.0 and Part D Policy 320.0D for Actemra IV as follows:

Note to Reviewer* If Actemra is being prescribed for COVID-19, see the FDA website for Emergency Use Authorizations at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs for current FDA authorized use. At this time, Actemra is authorized for inpatient use only for COVID-19 and would not be covered for outpatient use.

Veklury is currently available without a prior authorization as a medical benefit for Commercial, Marketplace, GHP Kids and GHP Family and a medical or pharmacy benefit for Geisinger Gold. No changes are recommended at this time.

The EUA for Olumiant is limited to inpatient use and Olumiant for the treatment of COVID-19 will be provided to inpatient pharmacies only by Lilly Authorized Specialty Distributors. Olumiant for the treatment of COVID-19 will not be available at retail pharmacies and is not authorized for outpatient use. The following note for the reviewer should be added to the Commercial Policy 530.0 and the Part D Policy 686.0D for Olumiant.

Note to Reviewer* If Olumiant is being prescribed for COVID-19, see the FDA website for Emergency Use Authorizations at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs for current FDA authorized use. At this time, Olumiant is authorized for inpatient use only for COVID-19 and would not be covered for outpatient use.

At this time, REGEN-COV, Casirivimab/imdevimab, and Bamlanivimab/etesevimab are unavailable in Darwin which is consistent with the current status of the EUA. No changes are needed at this time, since they are medical benefits and are not currently on the pharmacy formularies.

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

FAST FACTS

Caplyta (lumateperone)

Updated Indication: Caplyta is now FDA approved for the treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate

Previously this was only indicated for the treatment of schizophrenia in adults.

Current formulary status: Caplyta is a pharmacy benefit and is on the Brand Non-Preferred tier that requires prior authorization.

Recommendation: Recommend adding the following criteria to the Caplyta policy:

For Bipolar Depression

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of depressive episodes associated with bipolar I or bipolar II disorder (bipolar depression) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to quetiapine

Discussion: No comments or questions.

Outcome: The committee voted to accept the recommendations as presented. None were opposed.

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

Kisqali (ribociclib) & Kisqali Femara Co-pack (ribociclib/letrozole)

Updated Indication: Kisqali and Kisqali Femara Co-pack are now indicated for male patients. The indications have been revised as follows:

Kisqali is indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)- negative advanced or metastatic cancer in combination with:

- An aromatase inhibitor as initial endocrine-based therapy or
- Fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men

Kisqali Femara Co-pack is indicated as initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)- negative advanced or metastatic breast cancer.

Current formulary status: Kisqali and Kisqali Femara Co-pack: Oral Oncology Brand NP tier ($0 Copay), requires PA

Recommendation: There are no changes recommended for the formulary placement, quantity limits, and authorization duration of Kisqali or Kisqali Femara Co-pack. The following changes are recommended for Commercial Policy 447.0 to incorporate the new male patient population for Kisqali.

- Medical record documentation that Kisqali is prescribed by an oncologist **AND**
- Medical record documentation of diagnosis of hormone-receptor (HR) positive, HER2- negative, advanced or metastatic breast cancer **AND**
- Medical record documentation that Kisqali is being prescribed as initial endocrine therapy **AND**
- Medical record documentation that Kisqali will be used in combination with an aromatase inhibitor or fulvestrant **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of postmenopausal status **OR**
    - Medical record documentation of pre/perimenopausal status or member is male **AND** that member will be treated with ovarian ablation or suppression with a luteinizing hormone-releasing hormone (LHRH) agonist AND

Kisqali Following Disease Progression on Endocrine Therapy

- Medical record documentation that Kisqali is prescribed by an oncologist **AND**
- Medical record documentation of diagnosis of hormone-receptor (HR) positive, HER2- negative, advanced or metastatic breast cancer **AND**
- Medical record documentation that Kisqali is being prescribed after disease progression following endocrine therapy **AND**
- Medical record documentation that Kisqali will be used in combination with fulvestrant **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of postmenopausal status **OR**
    - Medical record documentation of pre/perimenopausal status or member is male **AND** that member will be treated with ovarian ablation or suppression with a luteinizing hormone-releasing hormone (LHRH) agonist

Discussion: No comments or questions.

Outcome: The committee voted to accept the recommendations as presented. None were opposed.

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

Voting responses were received from 30 of 44 members. The vote was unanimously approved.

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on March 15th, 2022 at 1:00 p.m.

Meeting will be via phone/Microsoft Teams