denotes change in current criteria
denotes new criteria

Atorvaliq (atorvastatin suspension)

Atorvaliq may be authorized for children who are 6-10 years of age who are unable to ingest solid dosage forms. Therapy may be authorized for older patients with clinical documentation indicating oral-motor difficulties or dysphagia.

STATINS		
atorvastatin lovastatin pravastatin rosuvastatin simvastatin**	ALTOPREV (lovastatin) ATORVALIQ (atorvastatin)*** CRESTOR (rosuvastatin) EZALLOR SPRINKLE (rosuvastatin)* fluvastatin fluvastatin ER LESCOL XL (fluvastatin) LIPITOR (atorvastatin) LIVALO (pitavastatin) PRAVACHOL (pravastatin) ZOCOR (simvastatin)** ZYPITAMAG (pitavastatin)	Non-preferred agents require twelve (12) week trials of two (2) preferred agents, including the generic formulation of the requested non-preferred agent, before they will be approved, unless one (1) of the exceptions on the PA form is present. *Ezallor SPRINKLE will only be authorized for those who are unable to ingest solid dosage forms due to documented oral-motor difficulties or dysphagia. **Zocor/simvastatin 80mg tablets will require a clinical PA. ***Atorvaliq may be authorized for children who are 6-10 years of age who are unable to ingest solid dosage forms. Therapy may be authorized for older patients with clinical documentation indicating oral-motor difficulties or dysphagia.

denotes change in current criteria
denotes new criteria

Hereditary Angioedema agents (treatment)- Berinert

RUCONEST is a C1 esterase inhibitor (recombinant) indicated for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE).

BERINERT is a plasma-derived C1 Esterase Inhibitor (Human) indicated for the treatment of acute abdominal, facial, or laryngeal hereditary angioedema (HAE) attacks in adult and pediatric patients.

CRITERIA FOR APPROVAL:

1) Diagnosis of hereditary angioedema (HAE) must be clinically established by, or in consultation with, an allergist, immunologist, hematologist or dermatologist; **AND**

2) Patient must be 13 years of age or older (for Ruconest) or 6 years of age or older (for Berinert); **AND**

3) Diagnosis of HAE is documented based on laboratory evidence of one of the following:

a. Low C4 level and a low C1 inhibitor (C1-INH) antigenic level; or

b. Low C4 level, normal C1-INH antigenic level and low C1-INH functional level; or

c. Normal C4, normal C1-INH antigenic level, normal C1-INH AND documentation of family history of hereditary angioedema or HAE causing mutation; **AND**

4) ~~Patient must be experiencing at least one symptom of a moderate or severe attack (non-laryngeal) (i.e. swelling of the face or abdomen)~~

Patient presents with at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives; **AND**

5) Baseline frequency of HAE attacks must be documented; **AND**

6) Patient is not concurrently taking an angiotensin converting enzyme (ACE) inhibitor, estrogen replacement therapy or any other medication known to potentially cause angioedema; **AND**

7) Patient is NOT concurrently on, or using in combination with, other approved treatments for acute HAE attacks; **AND**

8) **For Ruconest**: Patient does not have known or suspected allergies to rabbits or rabbit derived products.

denotes change in current criteria
denotes new criteria

Hereditary Angioedema agents (prophylaxis)

CINRYZE and HAEGARDA *are plasma-derived concentrates of C1 esterase inhibitor (human) (C1-INH) indicated for routine prophylaxis to prevent Hereditary Angioedema Attacks (HAE).*
TAKHZYRO *is a plasma kallikrein inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE).*

CRITERIA FOR APPROVAL:

1) The diagnosis of hereditary angioedema (HAE) must be clinically established by, or in consultation with, an allergist or immunologist; **AND**

2) The patient must meet the individual age restrictions outlined in the FDA-approved label for the requested agent; **AND**

3) Diagnosis of HAE must be documented and based on evidence of low C4 level AND one of the following:

a. A low C1 inhibitor (C1-INH) antigenic level; OR

b. A normal C1-INH antigenic level and a low C1-INH functional level;

AND

4) The member has a history of more than one moderate to severe attack per month (i.e. swelling of the face, throat, or abdomen); **AND**

5) Baseline frequency of HAE attacks must be documented; **AND**

6) The member is not concurrently taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy or any other medication known to cause potentially cause angioedema. ~~; AND~~

~~7) The recipient has had an insufficient response or contraindication to therapy with a 17α – alkylated androgen (e.g. danazol, stanozolol, oxandrolone, methyltestosterone).~~ **~~This requirement is waived for growing children and for pregnant or lactating females.~~**

denotes change in current criteria
denotes new criteria

Liqrev (sildenafil suspension)

Liqrev may be authorized for those who are unable to ingest solid dosage forms due to documented oral-motor difficulties or dysphagia AND documentation is provided as to why the clinical need cannot be met with either Revatio or sildenafil suspension.

PAH AGENTS – PDE5s[CL]		
CLASS PA CRITERIA: Non-preferred agents require a thirty (30) day trial of a preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present. - Patients stabilized on non-preferred agents will be grandfathered.		
sildenafil tablets	ADCIRCA (tadalafil) LIQREV (sildenafil)* REVATIO IV (sildenafil) REVATIO SUSPENSION (sildenafil) REVATIO TABLETS (sildenafil) sildenafil suspension (generic Revatio)** TADLIQ SUSPENSION (tadalafil)***	*Liqrev may be authorized for those who are unable to ingest solid dosage forms due to documented oral-motor difficulties or dysphagia AND documentation is provided as to why the clinical need cannot be met with either Revatio or sildenafil suspension. **sildenafil suspension may be authorized for those who are unable to ingest solid dosage forms due to documented oral-motor difficulties or dysphagia AND documentation is provided as to why the clinical need cannot be met with Revatio. ***Tadliq may be authorized for those who are unable to ingest solid dosage forms due to documented oral-motor difficulties or dysphagia AND after a thirty (30) day trial of Revatio resulting in an inadequate treatment response.

denotes change in current criteria
denotes new criteria

Zavzpret

Zavzpret may be authorized after a trial and failure of two (2) chemically distinct preferred triptans, unless contraindicated. One of the trials must include sumatriptan nasal spray.

OTHER		
NURTEC ODT (rimegepant)*	CAMBIA (diclofenac) D.H.E 45 AMPULE (dihydroergotamine)** dihydroergotamine injection, nasal spray** MIGERGOT RECTAL SUPPOSITORY (ergotamine/caffeine)** MIGRANAL SPRAY (dihydroergotamine)** REYVOW (lasmiditan)** TRUDHESA SPRAY (dihydroergotamine)** UBRELVY (ubrogepant)*** ZAVZPRET (zavegepant) nasal spray*****	*Nurtec ODT For a diagnosis of **Migraine treatment**: requires three (3) day trials of two (2) preferred chemically distinct triptans before it may be approved, unless one (1) of the exceptions on the PA form is present. Maximum Quantity limit of 8 tablets per 30 days. **All non-preferred Ergot alkaloid agents require three (3) day trials of (2) preferred triptans as well as a three (3) day trial of a preferred triptan using the same route of administration as the requested agent (if available), before they will be approved, unless one (1) of the exceptions on the PA form is present. **Note: Ergot derivatives should not be used with or within 24 hours of triptans.** **Additional Ergot Alkaloid criteria:** **Nasal spray:** dihydroergotamine nasal spray and Trudhesa spray may only be authorized after a trial and failure of Migranal spray. **Rectal suppository:** Migerot rectal suppository may only be authorized after a trial and failure of a preferred triptan nasal spray. **Injection:** dihydroergotamine injection and D.H.E 45 ampule may only be approved for cluster headaches. ***Ubrelvy and Reyvow require three (3) day trials of two (2) preferred chemically distinct triptans as well as a three (3) day trial of Nurtec ODT before they may be approved, unless one (1) of the exceptions on the PA form is present.

			Zavzpret may be authorized after a trial and failure of two (2) chemically distinct preferred triptans, unless contraindicated. One of the trials must include sumatriptan nasal spray.

denotes change in current criteria
denotes new criteria

Vowst (fecal microbiota spores, live-brpk)

VOWST is indicated to prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI).

Limitation of Use: VOWST is not indicated for treatment of CDI.

CRITERIA FOR APPROVAL:

1. The patient has a confirmed diagnosis of recurrent Clostridioides difficile infection with a total of ≥3 episodes of CDI within 12 months; **AND**

2. The CDI episodes were defined as diarrhea (≥3 unformed stools per day for at least 2 consecutive days) and a positive C. difficile stool sample using a toxin assay; **AND**

3. ~~Vowst is being prescribed by a gastroenterologist or infectious disease physician; **AND**~~

4. The patient is within the age range as recommended by the FDA label; **AND**

5. For prior CDIs patient has been trialed on the following regimen:

   Primary episode of CDI: Completed one or more round(s) of standard-of-care antibiotic therapy (e.g. metronidazole, vancomycin or fidaxomicin) **AND**

   For first or subsequent relapse: Completed a round of pulsed-dosed fidaxomicin (200 mg orally twice daily for 5 days, followed by once every other day for 20 days).

Requests for an additional course of Vowst therapy may only be authorized if the following criteria has been met:

1. The patient must have at least two relapses with documentation of CDI (as defined above) following Vowst treatment; **AND**

2. The patient must have completed an additional round on pulsed dosed fidaxomicin and trialed on Zinplava (either for the same episode or separate episodes).

Requests for additional therapy after treatment with a second course of Vowst will not be authorized within the subsequent year. Alternative treatment options should be considered.

denotes change in current criteria
denotes new criteria

Synagis

Palivizumab (Synagis) is a respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody indicated for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease.

APPROVAL CRITERIA:

- A patient-specific, clinically significant reason why the member cannot receive Beyfortus (nirsevimab-alip), as recommended by the CDC, must be provided. Additionally, the prescriber must confirm the member has not already received Beyfortus for the current RSV season. **Concomitant use with Beyfortus will not be approved; AND**

- The patient must meet criteria as outlined in the chart below.

LENGTH OF AUTHORIZATION:

- ~~Authorize for A maximum of five (5) doses during RSV reason (five monthly doses of 15 mg/kg IM).~~
- ~~In infants and children less than 24 months already on prophylaxis and eligible, one post-op dose can be approved after cardiac bypass or after extracorporeal membrane oxygenation (ECMO).~~

- Approvals will be granted for the duration of 1 month until RSV season ends. A separate prior authorization request will be required for consideration of initial approval and for each subsequent approval.

- Members initially approved for palivizumab will require a patient specific, clinically significant reason why the member still cannot receive Beyfortus (nirsevimab-alip).

RSV SEASON:

- Generally considered to run from November to April. WV Medicaid will provide coverage for qualifying prescriptions until March 31st. If approved, a maximum of five (5) doses during RSV season provides six (6) months of RSV prophylaxis.

- ~~Only a maximum of five (5) doses will be approved during RSV season.~~ If prophylaxis is initiated later in the RSV season, the infant or child will receive less than five (5) doses. For example, if prophylaxis is initiated in January, the 3rd and final dose, will be administered in March. For eligible infants born during RSV season, fewer than five (5) monthly doses may be needed.

denotes change in current criteria
denotes new criteria

Infant/Child Age at Start of RSV Season	Criteria
≤12 months (1st year of life)	▪ GA <29 wks, 0 d (otherwise healthy) ▪ CLD of prematurity (GA <32 wks, 0 d requiring >21% supplemental O_2 x first 28 d after birth) ▪ Anatomic pulmonary abnormalities, or neuromuscular disorder, or congenital anomaly that impairs the ability to clear secretions ▪ Profoundly immunocompromised ▪ CF with CLD and/or nutritional compromise ▪ CHD (hemodynamically *significant*) with *acyanotic* HD on CHF medications and who will require cardiac surgery or who have moderate to severe PH. For *cyanotic* heart defects consult a pediatric cardiologist
>12 months to ≤ 24 months (2nd year of life)	▪ CLD of prematurity (GA <32 wks, 0 d and >21% O_2 x first 28 d after birth) and medical support (chronic systemic steroids, diuretic therapy, or supplemental O_2) within 6 months before start of 2nd RSV season ▪ CF with severe lung disease* or weight for length <10th percentile ▪ Cardiac transplant during RSV season ▪ Already on prophylaxis and eligible: give post-op dose after cardiac bypass or after ECMO ▪ Profoundly immunocompromised

GA=gestational age; wks=weeks; d=day; CLD=chronic lung disease; CHD=congenital heart disease; O_2=oxygen; HD=heart disease; CHF=congestive heart failure; PH=pulmonary hypertension; CF=cystic fibrosis; ECMO=extracorporeal membrane oxygenation

* Examples of severe lung disease: previous hospitalization for pulmonary exacerbation in the 1st year of life, abnormalities on chest radiography [chest X-ray], or chest computed tomography [chest CT] that persist when stable

Denial Criteria – Palivizumab will NOT be approved in the following scenarios

Infant/Child Age at Start of RSV Season	Deny
>12 months to ≤ 24 months (2nd year of life)	▪ Based on prematurity alone ▪ CLD without medical support (chronic systemic steroids, diuretic therapy, or supplemental O_2) ▪ CHD ▪ Otherwise healthy children in 2nd year of life
Any age	▪ Breakthrough RSV hospitalization** ▪ Hemodynamically *insignificant* CHD*** ▪ CHD lesions corrected by surgery (unless on CHF meds) ▪ CHD and mild cardiomyopathy not on medical therapy ▪ CHD in 2nd year of life
No specific age defined	▪ GA ≥29 wks, 0 d (otherwise healthy) ▪ Asthma prevention

denotes change in current criteria
denotes new criteria

	▪ Reduce wheezing episodes ▪ Down Syndrome ▪ CF (otherwise healthy) ▪ Healthcare-associated RSV disease****

** If any infant or child is receiving palivizumab prophylaxis and experiences a breakthrough RSV hospitalization, discontinue palivizumab, because the likelihood of a second RSV hospitalization in the same season is extremely low.

*** Examples of hemodynamically *insignificant* CHD: secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, patent ductus arteriosus.

**** No rigorous data exist to support palivizumab use in controlling outbreaks of health care-associated disease; palivizumab use is not recommended for this purpose.