STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

Afinitor® and Afinitor Disperz® (everolimus)

Approvable indications for Afinitor

1. Approvable for members 18 years of age or older with a diagnosis of advanced renal cell carcinoma (kidney cancer) who have failed therapy with sunitinib (Sutent) or sorafenib (Nexavar); **or**
2. Approvable for members 1 year of age or older with a diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tubular sclerosis complex (TSC) who are not candidates for curative surgical resection; **or**
3. Approvable for members 18 years of age or older with a diagnosis of renal angiomyolipomas associated with tubular sclerosis complex (TSC) who do not require immediate surgery; **or**
4. Approvable for members 18 years of age or older with a diagnosis of progressive neuroendocrine tumors of pancreatic origin (PNET) that are unresectable, locally advanced or metastatic; **or**
5. Approvable for postmenopausal woman with a diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer in combination with exemestane (Aromasin) after failure of treatment with letrozole (Femara) or anastrozole (Arimidex).

For Afinitor Disperz

Approvable for members with a diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tubular sclerosis complex (TSC) who are not candidates for curative surgical resection. Members older than 10 years of age must be unable to swallow solid dosage forms (tablets) in order for the Disperz formulation to be approved.

References

1) Afinitor package insert. Indications and usage. Novartis Pharmaceuticals. 7/2014 http://www.pharma.us.novartis.com/product/pi/pdf/afinitor.pdf

Reviewed and Approved
Drug Utilization Review Board
September 17th, 2014

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

Anoro Elipta®
(umeclidinium-vilanterol inhalation powder)

ANORO ELLIPTA is a combination of umeclidinium, a long-acting anticholinergic, and vilanterol, a long-acting beta 2-adrenergic agonist (LABA). Anoro Ellipta is indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).

Criteria for Approval

1) Patient must be ≥18 years of age; **AND**
2) Patient must have had a diagnosis of COPD in the past 2 years; **AND**
3) Patient must have had 30 day trials of our preferred LABAs (Foradil or Serevent), or a preferred combination drug containing a LABA (like Advair) PLUS our preferred long-acting anticholinergic (Spiriva); **AND**
4) Patient must be receiving corticosteroid therapy unless there is a contraindication or intolerance.
5) Prior-authorization will be denied for patients diagnosed with asthma

References

1) Anoro Ellipta package insert 05/2014
2) Lexi-Comp Clinical Application September 2014
3) *Detail-Document;* Pharmacist's Letter 2014; 30(4):300403

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

Dalvance®
(dalbavancin)

Dalvance is lipoglycopepetide indicated for the treatment of acute bacterial skin and skin structure infections caused by susceptible gram-positive microorganisms, including MRSA.

Criteria for Approval

1) Appropriate documentation must be submitted with request. Documentation must list creatinine clearance and bacterial susceptibility (if known)
2) Patient must not have allergies listed to vancomycin or televancin (Vibativ)

References

4) Dalvance package insert 03/2014
5) Lexi-Comp Clinical Application September 2014
6) *PL Detail-Document* #300812

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STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

Duavee®
(conjugated estrogens/bazedoxifene)

Approvable Indications and Associated Criteria

1. Shall be approved for the prevention of postmenopausal osteoporosis in women with an intact uterus who have experienced ineffectiveness, allergies, contraindications, drug-drug interactions, or a history of intolerable side effects to Evista (raloxifene) AND generic Fosamax (alendronate); **OR**

2. Shall be approved for the treatment of moderate-to-severe vasomotor symptoms associated with menopause in women with an intact uterus who have experienced ineffectiveness, contraindications, drug-drug interactions, or a history of intolerable side effects to at least two (2) other estrogen/progestin products *

* Allergies to other estrogen products will not be sufficient cause to authorize Duavee, as it also contains estrogen.

Duavee will not be approved if any of the following is present

1. Undiagnosed abnormal uterine bleeding
2. Current or past history of venous thromboembolism (VTE) (e.g. PE, DVT)
3. Current or past history of arterial thromboembolic disease (e.g. stroke, MI)
4. Known, suspected, or history of carcinoma of the breast
5. Presence of an estrogen-dependent tumor
6. Hepatic dysfunction or disease
7. Thrombophilic disorders (such as protein C, protein S, or antithrombin deficiency)

References

1) Duavee package insert 10/2013
2) Lexi-Comp Clinical Applications monograph September, 2014
3) *Detail-Document;* Pharmacist's Letter 2014; 30(3):300310

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September 17th, 2014

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

Linzess ®
(linaclotide)

Linzess® will be prior authorized if each the following criteria are met:

1. Diagnosis of chronic idiopathic constipation, with less than three spontaneous bowel movements per week; **or**
2. Diagnosis of Irritable Bowel Syndrome with Constipation (IBS-C);
   and
3. Patient is eighteen (18) years of age or older **and**
4. Documented failure of at least one month of therapy with osmotic or bulk forming laxatives **and**
5. Appropriate screening for colon cancer, history of bowel obstruction, hepatic or renal disease, hypothyroidism, pelvic floor abnormalities, and spinal cord abnormalities.

   Note: Linzess carries a pregnancy risk factor C

The initial approval will be authorized for a period of twelve weeks. After follow-up with the prescriber, authorization may be granted for a period of 12 months.

References

1) © Copyright 2012 Forest Laboratories, Inc.
2) PL-Detail Document, New Drug:Linzess (Linaclotide)
3) Pharmacist's/Prescriber's Letter, December 2012

Reviewed and Approved
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September 17th, 2014

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Prior Authorization Criteria
Olysio™ (Simeprevir) for Hepatitis C (HCV)

Criteria for Approval

1) Patient must have a diagnosis of chronic hepatitis virus (HCV) genotype 1; **AND**
2) Olysio must be prescribed by, or in conjunction with, a board certified gastroenterologist, hepatologist or infectious disease physician; **AND**
3) Patient CANNOT have failed therapy with an oral protease inhibitor indicated for HCV (e.g., Incivek®, Victrelis®, or Olysio); **AND**
4) Olysio will only be authorized as part of a combination regimen. (See Table 1 for covered regimens)
5) If used in a regimen NOT containing Sovaldi, then the patient must not be infected with HCV genotype 1a containing the Q80K polymorphism.
6) Olysio will **not** be authorized if the patient is co-infected with HIV
7) Patient must be eighteen (18) years of age or older; **AND**
8) Patient may not be pregnant, as verified by a negative pregnancy test. In addition, the patient must attest that two forms of birth control will be used to prevent pregnancy during the treatment as indicated by the patient's signature on the Patient Consent Form; **AND**
9) Patient has abstained from the use of illicit drugs and alcohol for a minimum of six (6) months, as indicated by the patient's signature on the Patient Consent form; **AND**
10) Patient must be vaccinated against Hepatitis A and Hepatitis B; **AND**
11) Patient meets the diagnosis and disease severity criteria (≥F3 fibrosis indicating cirrhosis or bridging fibrosis) as outlined in Table 1; **AND**
12) Patient must agree to complete regimen (as outlined in Table 1) and the patient and the provider must agree that an SVR12 and SVR24 will be collected and submitted to WV Medicaid to verify therapy success;

Duration of Approval

- Initial approval is for 6 weeks and maximum approval duration is 12 weeks for simeprevir.
- Continued coverage beyond the initial approval depends on receipt of the HCV RNA level at treatment week 4 (TW4), documentation of patient compliance and continued abstinence. The HCV RNA must remain < 25 IU/ml.
- After discontinuation of simeprevir at week 12, it is expected that an HCV RNA at TW 12 will also be collected to evaluate continuation of ribavirin and peginterferon.

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Table 1 – Covered Regimens		
Documented HCV Genotype / Fibrosis Stage		
Diagnosis	**Approved Treatment Regimen**	**Regimen Duration**
HCV genotype 1 / ≥ Stage F3 (cirrhosis or bridging fibrosis)		
• Treatment naïve patients infected with HCV with or without compensated cirrhosis	*Triple Therapy* simeprevir + peginterferon alfa + ribavirin*	12 weeks of simeprevir with an additional 12 weeks of interferon + ribavrin
	Dual Therapy (interferon-ineligible) sofosbuvir + simeprevir	12 weeks

Diagnostic/Disease Severity Evidence (must be attached to request)

1) Cirrhosis may be substantiated either through biopsy or the presence of **at least two** of the following clinical features:
    a. Cirrhotic features on imaging
    b. Ascites
    c. Esophageal varices
    d. Reversed AST:ALT ratio (> 1), thrombocytopenia (< 130,000 platelets/μL), and coagulopathy (INR > 2)
2) Fibrosis level of F3 (indicating bridging fibrosis) must be substantiated via biopsy or other accepted method (e.g. FibroSure Assay)

Criteria for Denial

1) Patient is pregnant.

2) Patient has not abstained from the use of illicit drugs and/or alcohol for at least six (6) months prior to the start of treatment, as evidenced by an accepted laboratory screening test.
3) Patient has previously failed hepatitis protease inhibitor therapy (e.g. telaprevir (Incivek), boceprevir (Victrelis), simeprevir (Olysio)).
4) Patient has decompensated cirrhosis (defined as a Child-Pugh score greater than 6 [class B or C]).
5) Patient has severe renal impairment (eGFR < 30 mL/min/1.73m2) or end stage renal disease (ESRD) requiring hemodialysis.
6) Patient is post-liver transplant (safety and efficacy have not been established).
7) Patient has HCV genotype 2,3,4,5, or 6.
8) Patient is taking any concomitant medication that has a significant clinical interaction with simeprevir.
9) Patient refuses treatment with Interferon but does not meet definition of Interferon Ineligibility. **Interferon Alfa Ineligible** is defined as:
    a. Intolerance to interferon alfa – patient must have documented trial
    b. Autoimmune hepatitis and other autoimmune disorders
    c. Hypersensitivity to peginterferon alfa or any of its components
    d. Decompensated hepatic disease
    e. A baseline neutrophil count below 1,500/µL, a baseline platelet count below 90,000/µL or baseline hemoglobin below 10 g/dL

Additional Considerations

1) Simeprevir combination treatment with ribavirin or peginterferon alfa/ribavirin is contraindicated in women who are pregnant or may become pregnant and men whose female partners are pregnant because of the risks for birth defects and fetal death associated with ribavirin.
2) Simeprevir is an HCV NS3/4A protease inhibitor.
3) Coverage shall be for one course of therapy in a lifetime. Exceptions may be considered on a case-by-case basis.
4) Lost or stolen medication replacement request will not be authorized.

References

1) Olysio [package insert]. Janssen Therapeutics; Titusville, NJ. November 2013.
2) Sovaldi [package insert]. Foster City, CA; Gilead, December 2013.

3) American Association for the Study of Liver Diseases Infectious Diseases Society of America: Recommendations for testing, managing and treating hepatitis C. Available at: http://www.hcvguidelines.org/. Accessed April 22, 2014.
4) The alcohol use disorders identification test. AUDIT C test. Available at: http://www.hepatitis.va.gov/provider/tools/audit-c.asp Accessed April 25, 2014.
5) Brief counseling for alcohol misuse. Available at: http://www.hepatitis.va.gov/products/video-alcohol-brief-counseling.asp. Accessed April 25, 2014.
6) Helping patients who drink too much. A clinician's guide. US Department of Health and Human Services. National Institute of Alcohol Abuse and Alcoholism. 2005. Available at: http://pubs.niaaa.nih.gov/publications/Practitioner/CliniciansGuide2005/clinicians_guide.htm. Accessed April 25, 2014.
7) Clinician's screening tool for drug use in general medical settings. NIDA drug screening tool. National Institutes of Health National Institute on Drug Abuse. Available at: http://www.drugabuse.gov/nmassist/. Accessed April 25, 2014.
8) Theise ND. Liver biopsy assessment in chronic viral hepatitis: a personal, practical approach. Modern Pathology. 2007; 20: S3–S14.
9) European Association of the Study of the Liver. EASL recommendations on treatment of hepatitis C 2014. April 2014. Available at: http://files.easl.eu/easl-recommendations-on-treatment-of-hepatitis-C/index.html. Accessed April 23, 2014.
10) World Health Organization. Guidelines for the screening, care and treatment of persons with hepatitis C infection. April 2014. Available at: http://apps.who.int/iris/bitstream/10665/111747/1/9789241548755_eng.pdf?ua=1. Accessed April 23, 2014.
11) Shiffman ML, Benhanou Y. HCV F1/F2 patients: treat now or continue to wait. Liver International. 2014; ISSN 1478-3223. 79-84. doi:10.1111/liv.12408.
12) Chronic Hepatitis C virus (HCV) infection: treatment considerations from the Department of Veterans Affairs National Hepatitis C Resource Center Program and the Office of Public Health. March 27, 2014; data last reviewed on March 6, 2014.

Reviewed and Approved
Drug Utilization Review Board
September 17th, 2014

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

Otezla®
(apremilast)

Otezla is an inhibitor of phosphodiesterase 4 (PDE4) and is indicated for the treatment of adults with active psoriatic arthritis.

Criteria for Approval

6) Must be prescribed by a specialist (i.e a rheumatologist or dermatologist); **AND**
7) Patient must be ≥18 years old and diagnosed with active psoriatic arthritis; **AND**
8) Patient must have documented failure, intolerance or contraindications to NSAIDs; **AND**
9) Patient must have failed a sixty (60) day trial of a non-biological disease modifying anti-rheumatic drug (DMARD) such as methotrexate, sulfasalazine, leflunomide, or cyclosporine; **AND**
10) Patient must have failed ninety day trials of at least two (2) preferred biological DMARDs.

References

7) Otezla package insert 03/2014
8) Lexi-Comp Clinical Application September 2014

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September 17th, 2014

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Prior Authorization Criteria
Sovaldi™ (Sofosbuvir) for Hepatitis C (HCV)

Criteria for Approval

1) Sovaldi must be prescribed by, or in conjunction with, a board certified gastroenterologist, hepatologist or infectious disease physician; **and**
2) Patient is sofosbuvir treatment naïve; **and**
3) Patient must be eighteen (18) years of age or older; **and**
4) Patient may not be pregnant, as verified by a negative pregnancy test. In addition, the patient must attest that two forms of birth control will be used to prevent pregnancy during the treatment as indicated by the patient's signature on the Patient Consent Form; **and**
5) Patient has abstained from the use of illicit drugs and alcohol for a minimum of six (6) months, as indicated by the patient's signature on the Patient Consent form; **and**
6) Patient must be vaccinated against Hepatitis A and Hepatitis B; **and**
7) Patient meets the diagnosis and disease severity criteria (≥F3 fibrosis indicating cirrhosis or bridging fibrosis) as outlined in Table 1; **and**
8) Patient must agree to complete regimen (as outlined in Table 1) and the patient and the provider must agree that an SVR12 and SVR24 will be collected and submitted to WV Medicaid to verify therapy success;
9) For HIV-1 co-infected patients, patients must have the following:
    a. CD4 count greater than 500 cells/mm3, if patient is not taking antiretroviral therapy; **or**
    b. CD4 count greater than 200 cells/mm3, if patient is virologically suppressed (e.g., HIV RNA < 200 copies/mL)

Duration of Approval

Initial approval is for 6 weeks except for patients with hepatocellular carcinoma awaiting liver transplant, who will receive 12 weeks initial approval. All indications require submission of an HCV RNA level at treatment week 4 (TW4). Continued coverage depends on documentation of patient compliance, continued abstinence and an HCV RNA < 25 IU/ml. Patients awaiting transplant must also submit HCV RNA levels at TW12, TW24 and TW36.

Based on HCV genotype **(see Table 1 – Covered Regimens)**

a) Genotypes 1, 2, and 4 (including HCV-HIV-1 co-infection)
    i. 12 weeks, maximum
b) Genotype 3 (including HCV-HIV-1 co-infection)
    i. 12 weeks, maximum
c) Hepatocellular carcinoma awaiting liver transplant
    i. 48 weeks, maximum (or until transplant).

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Table 1 – Covered Regimens		
Documented HCV Genotype / Fibrosis Stage		
Diagnosis	**Approved Treatment Regimen**	**Regimen Duration**
HCV genotype 1 / ≥ Stage F3 (cirrhosis or bridging fibrosis)		
• HCV with or without compensated cirrhosis (incl. hepatocellular carcinoma [HCC]) • HCV/HIV-1 co-infection – Simeprevir will **NOT** be authorized in the presence of HIV co-infection	*Triple Therapy* sofosbuvir + peginterferon alfa + ribavirin* *Dual Therapy* (interferon-ineligible) sofosbuvir + simeprevir *Dual Therapy* (interferon-ineligible with HIV) Sofosbuvir + ribavirin	12 weeks 12 weeks 24 weeks
HCV genotype 2 / ≥ Stage F3 (cirrhosis or bridging fibrosis)		
• HCV with or without compensated cirrhosis (incl. HCC) • HCV/HIV-1 co-infection	*Dual Therapy* sofosbuvir + ribavirin*	12 weeks
HCV genotype 3 / ≥ Stage F3 (cirrhosis or bridging fibrosis)		
• HCV with or without compensated cirrhosis (incl. HCC) • HCV/HIV-1 co-infection	*Triple Therapy* sofosbuvir + peginterferon alfa +_ribavirin*	12 weeks
HCV genotype 4 / ≥ Stage F3 (cirrhosis or bridging fibrosis)		
• HCV with or without compensated cirrhosis (incl. HCC) • HCV/HIV-1 co-infection	*Triple Therapy* sofosbuvir + peginterferon alfa + ribavirin*	12 weeks
HCV genotype 1, 2, 3, or 4 – (Patient awaiting liver transplantation)		
• Hepatocellular carcinoma awaiting liver transplantation **and** • Meets Milan criteria: • In single hepatocellular (HC) carcinomas, tumor < 5 cm in diameter, **or** • In multiple HC carcinomas, no more than 3 tumor modules, each < 3 cm in diameter, **and** • No extra-hepatic manifestations of the cancer and no evidence of vascular invasion of the tumor.	*Dual Therapy* sofosbuvir + ribavirin*	48 weeks *or until the time of liver transplantation, whichever occurs first*

*Weight based ribavirin
Quantity Limit: One 400 mg tablet per day (28 tablets/28 days)
ALL OTHER REGIMEN REQUESTS WILL BE CONSIDERED ON A CASE-BY-CASE BASIS

Diagnostic/Disease Severity Evidence (must be attached to request)

3) Cirrhosis may be substantiated either through biopsy or the presence of **at least two** of the following clinical features:
    a. Cirrhotic features on imaging
    b. Ascites
    c. Esophageal varices
    d. Reversed AST:ALT ratio (> 1), thrombocytopenia (< 130,000 platelets/μL), and coagulopathy (INR > 2)
4) Fibrosis level of F3 (indicating bridging fibrosis) must be substantiated via biopsy or other accepted method (e.g. FibroSure Assay)

Criteria for Denial

10) Patient is pregnant.
11) Patient has not abstained from the use of illicit drugs and/or alcohol for at least six (6) months prior to the start of treatment, as evidenced by an accepted laboratory screening test.
12) Patient is not sofosbuvir naïve.
13) Patient is receiving concomitant hepatitis protease inhibitor therapy (e.g. telaprevir (Incivek), boceprevir (Victrelis).
14) Patient has decompensated cirrhosis (defined as a Child-Pugh score greater than 6 [class B or C]).
15) Patient has severe renal impairment (eGFR < 30 mL/min/1.73m2) or end stage renal disease (ESRD) requiring hemodialysis.
16) Patient is post-liver transplant (safety and efficacy have not been established).
17) Patient has HCV genotype 5 or 6.
18) Patient is taking a concomitant medication that has a significant clinical interaction with sofosbuvir:
    a. tipranavir/ritonavir
    b. rifampin, rifabutin, rifapentine
    c. carbamazepine, phenytoin, phenobarbital, oxcarbazepine
    d. St. John's wort
19) Patient refuses treatment with Interferon but does not meet definition of Interferon Ineligibility. **Interferon Alfa Ineligible** is defined as:
    a. Intolerance to interferon alfa – patient must have documented trial
    b. Autoimmune hepatitis and other autoimmune disorders
    c. Hypersensitivity to peginterferon alfa or any of its components
    d. Decompensated hepatic disease

e. A baseline neutrophil count below 1,500/µL, a baseline platelet count below 90,000/µL or baseline hemoglobin below 10 g/dL

Additional Considerations

5) Sofosbuvir combination treatment with ribavirin or peginterferon alfa/ribavirin is contraindicated in women who are pregnant or may become pregnant and men whose female partners are pregnant because of the risks for birth defects and fetal death associated with ribavirin.
6) Sofosbuvir is a nucleotide analog NS5B polymerase inhibitor.
7) Coverage shall be for one course of therapy in a lifetime. Exceptions may be considered on a case-by-case basis.
8) Lost or stolen medication replacement request will not be authorized.

References

13) Sovaldi [package insert]. Foster City, CA; Gilead, December 2013.
14) FDA Antiviral Drugs Advisory Committee Meeting, October 25, 2013; Background Package for NDA 204671 sofosbuvir (GS-7977).
15) Lawitz E, Mangia A, Wyles D, et al. Sofosbuvir for previously untreated chronic hepatitis C infection. *N Engl J Med*. 2013; 368:1878-87. doi: 10.1056/NEJMoa1214853. Available at: http://www.nejm.org/doi/pdf/10.1056/NEJMoa1214853. Accessed January 2, 2014.
16) Jacobson IM, Gordon SC, Kowdley KV, et al. Sofosbuvir for hepatitis C genotype 2 or 3 in patients without treatment options. *N Engl J Med.* 2013;368:1867-77. doi: 10.1056/NEJMoa1214854. Available at: http://www.nejm.org/doi/pdf/10.1056/NEJMoa1214854. Accessed January 2, 2014.
17) American Association for the Study of Liver Diseases Infectious Diseases Society of America: Recommendations for testing, managing and treating hepatitis C. Available at: http://www.hcvguidelines.org/. Accessed February 18, 2014.
18) Poynard T, Ratziu V, Benmanov Y, DiMartino V, Bedossa P, Opolon P. Fibrosis in patients with hepatitis c: detection and significance. *Semin Liver Dis*. 2000;20(1). Retrieved from www.medscape.com. Accessed February 26, 2014.

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Revised July 23, 2014 v 2.0
Revised September 17, 2014 v 3.0

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

SYNAGIS®
(palivizumab)

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.

LENGTH OF AUTHORIZATION

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

RSV SEASON

- Generally considered to run from November to April. A maximum of 5 doses during RSV season provides 6 months of RSV prophylaxis.

Only a maximum of 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 5 doses. For example if prophylaxis is initiated in January, the 4th and final dose, will be administered in April. For eligible infants born during RSV season, fewer than 5 monthly doses may be needed.

Approval 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 and >21% 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
≤ 12 months (1st year of life)	▪ CHD (hemodynamically *significant*) with *acyanotic* HD on CHF medications and will require cardiac surgery or moderate to severe PH. For *cyanotic* heart defects consult a pediatric cardiologist
>12 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
<24 months (2nd year of life)	▪ 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 (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 ▪ 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.

REFERENCES

1. American Academy of Pediatrics. Position Statement. Updated guidance for palivizumab prophylaxis among Infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. Pediatrics 2014; 134;415. DOI: 10.1542/peds.2014-1665. Available at: http://pediatrics.aappublications.org/content/134/2/415.full.pdf+html?sid=c5cf7568-4302-4ccd-9c71-ea785e33e241. Accessed August 6, 2014.
2. American Academy of Pediatrics. Technical Report. Updated guidance for palivizumab prophylaxis among Infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. DOI: 10.1542/peds.2014-1666. Available at: http://pediatrics.aappublications.org/content/early/2014/07/23/peds.2014-1666. Accessed July 29, 2014.
3. Synagis [package insert]. Gaithersburg, MD; MedImmune; March 2014.
4. Clinical criteria recommendations from Magellan Medicaid Administration, Inc.; August, 2014.

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September 17th, 2014