Statement of Medical Necessity (SMN)

SYNAGIS® PALIVIZUMAB

SKYEMED PHARMACY & INFUSION SERVICES

1 Specialty Pharmacy Provider Name: SKYEMED PHARMACY Phone: 866-778-8255 Fax: 800-432-6614

2 Patient Information

Name (First, Last):	Primary Guardian:
DOB: SSN:	Secondary Guardian:
Gender: ☐ Male ☐ Female Primary Language: ☐ English ☐ Spanish ☐ Other:	Home Phone # / Mobile Phone #: /
Address Street:	Patient one of multiple births? ☐ Yes ☐ No
City:	If yes, is sibling(s) referral being submitted simultaneously? ☐ Yes ☐ No
State: ZIP:	Sibling Names:

3 Insurance Information

☐ No Insurance ☐ Include copies of front and back of Medical and Pharmacy cards *(If copies are included, you do not need to rewrite card information)*

	Primary Insurance	Secondary Insurance	Pharmacy Benefit
Insurance Name:			
Cardholder Name (if not patient) / DOB:			
Group #:			
Policy # / Patient ID #:	/	/	/
Insurance Phone #:			
BIN # / PCN # (pharmacy only):	/	/	/

Independent Practice Association (IPA) / Accountable Care Organization (ACO) (if applicable): /

4 Prescriber Information

	Treating	Referring (Optional)
Prescriber Name:		
Site Name:		
Office Contact:		
Telephone # / Fax #:	/	/
Address:		
NPI #:		
License # / Tax ID #:	/	/
Medicaid Provider # / DEA #:	/	/

5 Clinical Information

Patient's gestational age (GA) at birth: _____ Current weight: _____ kg _____ lbs-oz Date current weight recorded: _____

Diagnosis Code(s): _____

CLINICAL INFORMATION: Birth weight: _____ ☐ Medical records included

1. ☐ **BPD/CLDP: Diagnosis of bronchopulmonary dysplasia/chronic lung disease of prematurity and ≤24 months of age** (Specific Diagnosis Code: _____)
   Is patient receiving medical treatment? (check all that apply and provide last date received):
   ☐ Oxygen date: _____ ☐ Corticosteroids date: _____ ☐ Bronchodilators date: _____ ☐ Diuretics date: _____
2. ☐ **CHD: Diagnosis of hemodynamically significant congenital heart disease and ≤24 months of age** (Specific Diagnosis Code: _____)
   Patient has any of the following (check all that apply):
   ☐ Medications for CHD: _____ ☐ Moderate to severe pulmonary hypertension
   Date CHD medications were last received: _____ ☐ Cyanotic CHD
3. **Indicate applicable risk factors:**
   ☐ Congenital abnormality of airways ☐ Severe neuromuscular disease ☐ Pre-school or school-aged sibling(s) (<5 years of age)
   ☐ Family history of asthma or wheezing ☐ Residency in rural setting ☐ Daycare – care at any home or facility with any number of infants or young toddlers
   ☐ Multiple births ☐ Exposure to environmental tobacco smoke or air pollutants

6 Prescription Information

Please see Important Safety Information on the following page.

Was SYNAGIS® (palivizumab) previously administered? (NICU/hospital/other location) ☐ Yes ☐ No Date(s): _____

Expected date of first/next dose: _____

Deliver medicine to: ☐ Office ☐ Patient's home ☐ Clinic Clinic Name and Location: _____

Agency nurse to visit home for injection? ☐ Yes ☐ No Agency name and Tax ID #: _____

Rx SYNAGIS 50 mg and/or 100 mg vials. Inject 15 mg/kg IM one time per month. QS to achieve 15 mg/kg dose. **Refills: (Please enter "0" if no refills remain)** _____ Required *

☐ Epinephrine 1:1000 amp. Sig: Inject 0.01 mg/kg IM/SC as directed ☐ Known allergies: _____

☐ Ancillary supplies and kits as needed for administration: _____

Attestation of Authorization

By signing this form, I certify that I have the necessary authorization to release the information included on this form and other protected health information (as defined by HIPAA), and receive information on the status and related matters, to AstraZeneca's Access 360™, including employees, contractors, or affiliates of AstraZeneca, and health care plans for programs, dispensing pharmacy or other entities, for the purposes of treatment and payment support. If not already received, I give Access 360 permission to contact this patient to obtain Patient Authorization.

Required * **Original Signature of Prescriber:** _____ **Date:** _____ Required *

A Patient Support Program

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Access 360™

For Support, Please Contact Access 360:

1-844-ASK-A360 (1-844-275-2360)

www.MyAccess360.com

1-844-FAX-A360 (1-844-329-2360)

One MedImmune Way,
Gaithersburg, MD 20878

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This form should not be construed as coding advice. Each practitioner is solely responsible for ensuring the accuracy of the information submitted. New York prescribers must submit a state-approved prescription document with this completed form. Ohio prescribers should note that only one prescription per form is allowed. Please send additional prescriptions separately.

Important Safety Infomation

SYNAGIS® (palivizumab) is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease. Safety and efficacy were established in children with bronchopulmonary dysplasia (BPD), infants with a history of premature birth (≤35 weeks gestational age), and children with hemodynamically significant congenital heart disease (CHD). The recommended dose of SYNAGIS is 15 mg/kg of body weight given monthly by intramuscular injection. The first dose of SYNAGIS should be administered prior to commencement of the RSV season and the remaining doses should be administered monthly throughout the RSV season. Children who develop an RSV infection should continue to receive monthly doses throughout the RSV season.

The efficacy of SYNAGIS at doses less than 15 mg/kg, or of dosing less frequently than monthly throughout the RSV season, has not been established.

SYNAGIS is contraindicated in children who have had a previous significant hypersensitivity reaction to SYNAGIS. Cases of anaphylaxis and anaphylactic shock, including fatal cases, have been reported following initial exposure or re-exposure to SYNAGIS. Other acute hypersensitivity reactions, which may be severe, have also been reported on initial exposure or re-exposure to SYNAGIS. The relationship between these reactions and the development of antibodies to SYNAGIS is unknown. If a significant hypersensitivity reaction occurs with SYNAGIS, its use should be permanently discontinued. If a mild hypersensitivity reaction occurs, clinical judgment should be used regarding cautious readministration of SYNAGIS. As with any intramuscular injection, SYNAGIS should be given with caution to children with thrombocytopenia or any coagulation disorder. Palivizumab may interfere with immunological-based RSV diagnostic tests, such as some antigen detection-based assays.

Adverse reactions occurring greater than or equal to 10% and at least 1% more frequently than placebo are fever and rash. In post-marketing reports, cases of severe thrombocytopenia (platelet count <50,000/microliter) and injection site reactions have been reported.

Please see accompanying full Prescribing Information for SYNAGIS, including Patient Information.

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AstraZeneca

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