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CardinalCare
Virginia's Medicaid Program

COMMONWEALTH OF VIRGINIA DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Service Authorization (SA) Form

DUR MEDICATION SYNAGIS®

(Season: October 1, 2024 through March 31, 2025)

If the following information is not complete, correct, or legible, the SA process can be delayed.
Please use one form per member.

MEMBER INFORMATION

Last Name: _____

First Name: _____

Medicaid ID Number: _____

Diagnosis/ICD-10 Code: _____

Date of Birth: _____

Gestational Age: _____ **Weeks** _____ **Days**

Weight in Kilograms: _____

PRESCRIBER INFORMATION

Last Name: _____

First Name: _____

NPI Number: _____

Phone Number: _____

Fax Number: _____

DRUG INFORMATION

Drug Name/Form: _____

Strength: _____

Dosing Frequency: _____

Length of Therapy: _____

Quantity per Day: _____

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

DIAGNOSIS AND MEDICAL INFORMATION

Check applicable age, conditions, and risk factors:

- ☐ Gestational age < 28 weeks, 6 days and member's chronological age (CA)[1] < 12 months
- ☐ Chronic lung disease of prematurity (gestational age 32 weeks, 0 days) AND member's CA[1] < 12 months at start of RSV season and required > 21% oxygen for at least 28 days after birth
- ☐ Member's CA[1] < 12 months with congenital abnormalities of the airway or neuromuscular disease that compromises handling of respiratory secretions[2]
- ☐ Member's CA[1] < 24 months old with chronic lung disease[2] of prematurity (gestational age < 32 weeks)
- ☐ Member's CA[1] < 12 months old with hemodynamically congenital heart disease[2] (without surgical correction)
- ☐ Member's CA[1] < 24 months old AND severely immunocompromised

Answer the following questions:

1. Does the member or member's mother have a history of taking the RSV vaccine?
   ☐ Yes ☐ No
2. Has the member received a dose of nirsevimab (Beyfortus™) during the current RSV season?
   ☐ Yes ☐ No
3. Is the member currently an outpatient without an inpatient hospitalization within the last 2 weeks?
   ☐ Yes ☐ No
   *If **no**, document the discharge date:* _____
4. Has the member received any Synagis® doses during the current RSV season?
   ☐ Yes ☐ No
   *If **yes**, document the administration date(s):* _____

Medical justification: Documentation for diagnoses not listed above (attach supporting documentation):

_____

_____

_____

_____

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

DIAGNOSIS AND MEDICAL INFORMATION *(continued)*

SYNAGIS® – to receive approval for this drug, answer the following questions:

1. Is the member's gestational age < 28 weeks, 6 days and is chronological age (CA)[1] less than 12 months?
   ☐ Yes (If YES, go to #7) ☐ No (If NO, go to #2)
2. Does the member have chronic lung disease of prematurity (gestational age < 32 weeks, 0 days) **AND** is member's CA[1] < 12 months old at start of RSV season **AND** did the member require > 21% oxygen for at least 28 days after birth?
   ☐ Yes (If YES, go to #7) ☐ No (If NO, go to #3)
3. Is the member's CA[1] < 12 months with a diagnosis[3] of congenital abnormalities of the airway or neuromuscular disease that compromises handling of respiratory secretions?
   ☐ Yes (If YES, go to #7) ☐ No (If NO, go to #4)
   Supporting documentation[4] of diagnosis/ICD-10 code must be included.
4. Is the member < 24 months of age with a diagnosis of chronic lung disease[3] (CLD) of prematurity (defined as gestational age < 32 weeks) **AND** has member received medical therapy (supplemental oxygen [> 21% for at least 28 days, vent not required], diuretic, or chronic corticosteroid therapy) within 6 months before the start of the RSV season **OR** does member continue to require medical therapy (as defined above)?
   ☐ Yes (If YES, indicate treatment below and go to #7) ☐ No (If NO, go to #5)
   Supporting documentation[4] of diagnosis/ICD-10 code and medical therapy must be included.
5. Is the member ≤ 12 months of age with a diagnosis of hemodynamically significant congenital heart disease (CHD) with one of the following?
   a. Congenital heart disease[3] and member is receiving medication to control congestive heart failure (CHF); **OR**
   b. Moderate to severe pulmonary hypertension[3]; **OR**
   c. Cyanotic heart disease with no or incomplete surgical correction of defect[3]

   ☐ Yes (If YES for 5a, 5b, or 5c, go to #7) ☐ No (If NO, go to #6)
   Supporting documentation[4] of diagnosis/ICD-10 code as well as medications (if applicable) must be included.
6. Is the member < 24 months of age and severely immunocompromised?
   ☐ Yes (If YES, go to #7) ☐ No (If NO, must be reviewed by Pharmacist or Medical Director)
7. Is the member currently an outpatient who has not been enrolled as an inpatient within 2 weeks of the date the Synagis® is requested?
   ☐ Yes (If YES, approve request) ☐ No (If NO, SA must be given to be effective 2 weeks post-hospital discharge)
   Enter discharge date (if applicable): _____

Member's Last Name: **Member's First Name:**

One of the first six criteria and the final criterion must be met before approval can be granted. Documentation of the hospital discharge summary from birth or documentation of the first office visit with pertinent information (gestational age, diagnosis, etc.) is required on all Synagis® SA requests. RSV prophylaxis approval will terminate March 31. RSV season is defined by the Virginia Medicaid Agency as October 1 through March 31. Exceptions may be made if evidence of an atypical RSV season is identified in conjunction with the Virginia Department of Health.

NOTE: Approval authorizes up to a five-dose maximum. If additional doses are needed, another prior authorization is required. A dose is defined as the calculated dosage (member weight [kg] X 15 mg/kg divided by 100 mg/mL of Synagis®). The results of the calculation will be the number of mL the member needs. Use the appropriate combination of vials to get the correct dose. Requests for more than one dose in a 28-day period cannot be approved. If the member received a dose in an inpatient setting, approval will only be given for four doses. Letters will be faxed to both prescriber and dispensing pharmacy notating approval or denial.

Prescriber Signature (Required) **Date**

By signature, the physician confirms the above information is accurate and verifiable by member records.

Please include ALL requested information; Incomplete forms will delay the SA process.
Submission of documentation does NOT guarantee coverage by the Department of Medical Assistance Services.

The completed form may be: **FAXED TO 800-932-6651**, phoned to 800-932-6648, or mailed to:
Prime Therapeutics Management LLC
Attn: GV – 4201
P.O. Box 64811
St. Paul, MN 55164-0811

[1] Chronological age (CA) at the start of the RSV Season.

[2] Include ICD-10 codes for the indicated disease states. For CLD/CHD, attach supporting documentation (i.e., progress notes, discharge notes, and/or chart notes).

[3] Please refer to Appendix A of the Synagis® Service Authorization Instruction Worksheet for acceptable diagnosis/ICD-10 codes for all applicable diagnoses as well as acceptable medications used in CHD.

[4] Supporting documentation is supplemental information submitted to support the member meeting the criteria. Supporting documentation may include copies of hospital discharge notes, progress notes, pharmacy profiles, etc., and must include all medications, frequency of medication dosing, and diagnoses with indications of severity of illness.

Synagis® Service Authorization Instruction Worksheet

Palivizumab (hereby called by its trade name Synagis®) is FDA-approved for the prevention of respiratory syncytial virus (RSV) in select infants and children. Synagis® requires service authorization (SA) for reimbursement through the Virginia Medicaid Agency. The approval time frame for Synagis® will begin October 1 and will be effective through March 31 of the following year. Exceptions may be made if evidence of an atypical RSV season is identified in conjunction with the Virginia Department of Health. Synagis® should be administered monthly; a total of up to five doses will be allowed per recipient from October 1 through March 31. If additional doses are needed, another prior authorization is required.

For approval of requests, the recipient must meet gestational and chronological age requirements. In order to meet chronological age requirements, the recipient must be the required age at the start of the RSV season.

Prescribers—not the pharmacy, manufacturer, or any other third party entity—are to submit requests for Synagis® on a separate SA form or by phone **directly** to Prime Therapeutics Management LLC (Prime) and may be accepted beginning September 1 (for an October 1 effective date). Letters will be faxed to the prescriber notating approval or denial.

The following outlines the instructions and additional information for completing the Synagis® SA form. Questions regarding the Synagis® SA process can be directed to Prime at 1-800-932-6648.

Member Information

Complete the Member Information Section to include member name, Medicaid recipient ID #, date of birth, and phone number with area code.

Prescriber Information

Complete the Prescriber Information Section to include prescriber name, NPI, license #, phone and fax number, and address (optional). The prescriber **MUST** sign and date the SA form attesting the information on the submitted form and supplemental information is accurate information. Stamped signatures will not be accepted.

Drug/Clinical Information

Synagis® has been approved by Virginia Medicaid for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) as outlined by the American Academy of Pediatrics (AAP) recommendations[1] for the prevention of RSV.

The member must meet the most current AAP guidelines[1], the gestational age, chronological age, and must be an outpatient with no inpatient stay for at least two weeks prior to the date of the medication request. In order to meet chronological age requirements, the recipient must be the required age at the start of the RSV season.

See *Appendix A* of the Synagis® SA Instruction Worksheet for a list of diagnosis/ICD-10 codes and acceptable medications for use with the Synagis® SA form.

If a dose was administered in an inpatient setting, the date the dose was administered must be included on the SA request form.

See *Synagis® Service Authorization Criteria* for specific requirements for approval.

Required fields within this section of the SA form include:

- Drug requested strength
- Quantity per month
- Current weight of recipient (in kg)
- Gestational age (in weeks and days)
- Number of doses requested
- ICD-10 Code

Other fields within this section of the SA form are to be completed/marked if applicable.

SA Approval Timeframes

Approval may be given for up to five doses or through the end of RSV season (March 31), whichever comes first.

Prior Treatment Trials

Prior treatment trials do not apply to Synagis®.

Stable Therapy

Stable therapy does not apply to Synagis®. A new SA must be submitted for each defined Synagis® season.

Electronic Service Authorizations

Not applicable

Verbal SA Requests

Providers may submit verbal SA requests to Prime Therapeutics Management LLC at 1-800-932-6648.

Glossary:

Chronic Lung Disease (CLD), also known as bronchopulmonary dysplasia (BPD): an infant less than 32 weeks' gestation evaluated at 36 weeks' postmenstrual age or an infant of more than 32 weeks' gestation evaluated at more than 28 days but less than 56 days of age who has been receiving supplemental oxygen for more than 28 days[1]. CLD of prematurity is defined as CLD with gestational age less than 35 weeks[1].
Note: CLD **does not** include croup, URI, bronchitis, bronchiolitis, asthma, or wheezing.

Hemodynamically significant Congenital Heart Disease (CHD): children with congenital heart disease who are receiving medication to control congestive heart failure, have moderate to severe pulmonary hypertension, or have cyanotic heart disease[1]. Decisions regarding prophylaxis with Synagis® in children with CHD should be made based on the degree of physiologic cardiovascular compromise[1].

Medical Justification: an explanation of the reason the drug is required in a particular member and any additional information needed. Medical justification may include supporting documentation from the member chart or peer-reviewed literature to support the physician's request for the drug.

Supporting Documentation: supplemental information submitted to support the member meeting the criteria. Supporting documentation may include copies of hospital discharge notes, progress notes, pharmacy profiles, etc.

References

1. Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. Reaffirmed 2019. Pediatrics 2014 Aug 1; 134:415. http://pediatrics.aappublications.org/content/134/2/415.
2. RSV Policy Statement – Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. Reaffirmed 2019. Pediatrics 2014 December; 134:1221.

Appendix A: ICD-10 CODE and MEDICATION LIST FOR USE WITH SYNAGIS® CRITERIA

Note: ANY accepted diagnosis/ICD-10 Code listed on the service authorization form **MUST** have supporting documentation attached. Supporting Documentation is supplemental information submitted to support the member meeting the criteria and may include copies of hospital discharge notes, progress notes, and pharmacy profiles.

I. Neuromuscular Disorders

Acceptable ICD-10 codes include:

A80.30 – Infantile paralysis
G31.9 – Cerebral degenerations
G25.3 – Myoclonus
G11.1, G11.4 – Spinocerebellar disease
G12.0 – Werdnig-Hoffman disease (Infantile spinal muscular atrophy)
G12.1, G12.8, G12.9 – Spinal muscular atrophy
G12.2 – Motor neuron disease

Excludes (but not limited to) the following (i.e., the following are **NOT accepted**):

G80 – Cerebral Palsy
G40.3 – Generalized Convulsive epilepsy
G40.301 – Grand mal seizures
G40 – Epilepsy
Q05 – Spina bifida
P90 – Newborn seizures
R56 – Infantile seizures

II. Congenital Abnormalities of the Airways

Acceptable ICD-10 codes include:

Q32 – Other diseases of the trachea and bronchus, not elsewhere classified (Must specify Tracheomalacia or tracheal stenosis)
Q31, Q32 – Other anomalies of larynx, trachea, and bronchus (Must specify congenital tracheal stenosis, atresia of trachea, laryngomalacia, or absence or agenesis of bronchus, trachea)
Q33.0 – Congenital cystic lung
Q33.2, Q33.3, Q33.6 – Agenesis, hypoplasia, and dysplasia of the lung
Q33.4 – Congenital bronchiectasis
Q38.2 – Macroglossia
Q38.5 – Uvula anomaly
Q87.3 – Beckwith (-Wiedemann) Syndrome

Excludes (but not limited to) the following (i.e., the following are **NOT accepted**):

Q33.9 – Anomaly of lung, unspecified
Q33.1, Q33.5, Q33.8 – Other anomaly of the lung

III. Chronic Lung Disease

Acceptable ICD-10 code:

P27 – Chronic respiratory disease arising in the perinatal period (CLD/BPD/Interstitial pulmonary fibrosis of prematurity/Wilson-Mikity syndrome)

Excludes (but not limited to) the following (i.e., the following are **NOT accepted**):

J05.0 – Croup
J06 – URI
J20 – Bronchitis
J21 – Bronchiolitis
J45 – Asthma
R06.2 – Wheezing

IV. Congenital Heart Diseases (CHD)

Acceptable ICD-10 codes:

A. Acyanotic CHD: Must currently be receiving medication to control CHF (see below)

I35 – Aortic stenosis*
I42 – Cardiomyopathy (must be moderate to severe)
I27.83, Q21.0 – Ventricular septal defect*
Q21.1 – Atrial septal defect*
Q21.2 – Atrioventricular canal (endocardial cushion defect)
Q22.1 – Pulmonic stenosis*
Q25.0 – Patent ductus arteriosus*
Q25.1, Q25.21 – Coarctation of the aorta*

B. Cyanotic CHD: Does not require use of medication/must not have had or completed surgical correction

Q20.0 – Truncus arteriosus
Q20.3 – Transposition of the great vessels
Q21.3 – Tetralogy of Fallot
Q22.0 – Atresia, congenital
Q22.4, Q22.8, Q22.9 – Tricuspid atresia and stenosis, congenital
Q22.5 – Ebstein's anomaly
Q23.4 – Hypoplastic left heart
Q22.6 – Hypoplastic right heart
Q26.2 – Total anomalous pulmonary venous return

C. Pulmonary Hypertension:

I26.0 – Acute cor pulmonale
I27.0 – Primary pulmonary hypertension
I27.2 – Other chronic pulmonary heart disease (pulmonary hypertension, secondary)
P29.3 – Persistent fetal circulation (persistent pulmonary hypertension/primary pulmonary hypertension of newborn)

** Per AAP guidelines, decisions on prophylaxis with Synagis® in children with CHD should be made on the degree of cardiovascular compromise. CHD that is deemed hemodynamically insignificant will not meet criteria. Documentation must specifically support CHD being hemodynamically significant (e.g., medications).*