

## Policy and Procedure

<b>DEPARTMENT:</b> Pharmacy Operations, Medical Directors	<b>DOCUMENT NAME:</b> 2019-2020 Synagis® (Palivizumab) Season Policy
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<b>APPROVED DATE:</b>	<b>RETIRED:</b>
<b>EFFECTIVE DATE:</b>	<b>REVIEWED/REVISED:</b> 09/16, 9/17, 9/18, 12/18, 9/5/19, 10/24/19, 11/27/19
<b>PRODUCT TYPE:</b> STAR, STAR HEALTH, STAR PLUS, STAR Kids, CHIP	<b>REFERENCE NUMBER:</b> TX.PHAR.11

### IMPORTANT REMINDER

The purpose of this Clinical Policy is to provide a guide to medical necessity reviews for Synagis® under the pharmacy benefit. Clinical policies are intended to be reflective of current scientific research and clinical thinking and in accordance to state guidance. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

### Subject

Prior authorization of Synagis® for medical necessity in prevention of respiratory syncytial virus or RSV in certain at risk Members

### Description

The intent of the criteria is to ensure that patients follow selection elements established by the Texas Vendor Drug Program.

### FDA Approved Indications

Palivizumab is a prescription medication given intramuscularly that acts as passive immunity to help mediate the severity of RSV infection in infants at high-risk for complications. Palivizumab exhibits neutralizing and fusion-inhibitory activity against RSV by attaching to surface glycoproteins of the virus. These activities inhibit RSV replication. Each dose of palivizumab gives the high-risk infants passive immunity for about 30 days.

### Policy

It is the policy of Superior Healthplan to follow the Texas Vendor Drug Program clinical edit criteria for the 2019 – 2020 RSV season. All prior authorization requests will be handled by the Superior HealthPlan Pharmacy Department. Medications denials are reviewed by a Medical Director following existing policy and procedure for specialty medications. Medications with partial approvals (meaning not all quantity is approved such as excessive requests outside of the season dates) are reviewed by a Superior Pharmacist. A Superior Healthplan Prior Authorization form for the 2019-2020 RSV season can be found on our website. In addition, links to the county schedule and clinical edit criteria are also on our website. The Provider may use the Texas Standard Prior Authorization Form from the Texas Department of Insurance (TDI) for Prescription Drug Benefits. The Provider is encouraged to fill out the Synagis Addendum if the

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TDI PA form is used. This addendum supports the clinically necessary information Superior needs to properly review the PA request.

Synagis® is available through a limited distribution network as established by the manufacturer for all Star plans. AcariaHealth and CVS Caremark are the two specialty pharmacy providers contracted with Superior HealthPlan for Synagis®. Superior's preferred specialty pharmacy is AcariaHealth. The Provider will need to note the preference of specialty pharmacy from these two options on the prior authorization form. Providers should send a prescription for the medication directly to the specialty pharmacy for processing. All drug billing is made using the vendor PBM system. Providers may bill for the actual injection of the Member but the drug itself is covered by the pharmacy benefit.

Synagis® is only available through medical benefits for CHIP. This is not a covered benefit through pharmacy benefits.

Any authorization approvals will be entered into the vendor PBM system. Upon refill request, the specialty pharmacy will inquire with the Provider or Medical staff if there has been hospitalization(s) for RSV since the last fill of the medication. In addition, Superior Pharmacy staff will also check any claims report data for RSV hospitalizations. Any Member who has a confirmed hospitalization for RSV will not receive future doses this season. The authorization will be end dated in the vendor PBM system by the Superior Pharmacy team and the specialty pharmacy will cancel the pending refill and further refills for the season for the impacted Member.

### **Clinical Criteria:**

Clinical Criteria is followed directly from the Texas Vendor Drug Program guidance. A Superior HealthPlan Member may be approved for up to five doses per single authorization. As noted above any documented RSV hospitalization will negate the need for future refills as obtained via the specialty pharmacy and Provider discussion or via claims records.

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**Synagis® is only available through medical benefits for CHIP. This is not a covered benefit through pharmacy benefits.**

1. Is the client's chronological age less than (<) 12 months at the beginning of the RSV season for the client's county of residence?
  - Yes (Go to #2)
  - No (Go to #13)
2. Is the client's gestational age less than or equal to ( $\leq$ ) 28 6/7 weeks?
  - Yes (Go to #21)
  - No (Go to #3)
3. Does the client have a diagnosis of chronic lung disease (CLD) of prematurity?
  - Yes (Go to #4)
  - No (Go to #5)
4. Is the client's gestational age less than or equal to ( $\leq$ ) 31 6/7 weeks?
  - Yes (Go to #21)
  - No (Go to #5)
5. Does the client have a severe congenital abnormality of the airway?
  - Yes (Go to #21)
  - No (Go to #6)
6. Does the client have a diagnosis of severe neuromuscular disease that compromises the handling of respiratory tract secretions?
  - Yes (Go to #21)
  - No (Go to #7)
7. Does the client have a diagnosis of acyanotic heart disease?
  - Yes (Go to #8)
  - No (Go to #9)

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8. Does the client have 1 claim for a medication for heart disease in the last 60 days, AND will require cardiac surgery?
    - Yes (Go to #21)
    - No (Go to #9)
  9. Does the client have a diagnosis of moderate to severe pulmonary hypertension?
    - Yes (Go to #21)
    - No (Go to #10)
  10. Does the client have a diagnosis of cyanotic heart disease?
    - Yes (Go to #11)
    - No (Go to #12)
  11. Is prescribing provider a pediatric cardiologist or has the prescribing provider indicated that a pediatric cardiologist has been consulted?
    - Yes (Go to #21)
    - No (Go to #12)
  12. Does the client have a diagnosis of cystic fibrosis (CF) with clinical evidence of CLD and/or nutritional compromise?
    - Yes (Go to #21)
    - No (Go to #13)
  13. Is the client less than (<) 24 months of age at the beginning of the RSV season for the client's county of residence?
    - Yes (Go to #14)
    - No (Deny)
  14. Does the client have a diagnosis of an identified disease state that will leave them profoundly immunocompromised during the RSV season?
    - Yes (Go to #21)
    - No (Go to #15)
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15. Has the patient had a solid organ or hematopoietic stem cell transplant during the RSV season?
  - Yes (Go to #21)
  - No (Go to #16)
16. Is the client less than (<) 24 months chronological age and greater than or equal to (≥) 12 months chronological age at the beginning of the RSV season for the client's county of residence?
  - Yes (Go to #17)
  - No (Deny)
17. Does the client have a diagnosis of chronic lung disease (CLD) of prematurity?
  - Yes (Go to #18)
  - No (Go to #20)
18. Is the client's gestational age less than or equal to (≤) 31 6/7 weeks?
  - Yes (Go to #19)
  - No (Go to #20)
19. Does the client have a history of any of the following in the last 180 days: chronic use of systemic corticosteroids, diuretics, long-term mechanical ventilator, and/or supplemental oxygen?
  - Yes (Go to #21)
  - No (Go to #20)
20. Does the client have a diagnosis of cystic fibrosis (CF) with severe lung disease OR weight less than the 10<sup>th</sup> percentile?
  - Yes (Go to #21)
  - No (Deny)
21. Is the claim for 1 vial of either the 50mg or 100mg vials?
  - Yes (Go to #22)
  - No (Deny)

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22. Are there greater than (>) 4 dates of service for palivizumab since the beginning of the current RSV season (determined by client's county of residence) until today?
- Yes (Deny)
  - No (Approve – up to 5 total doses based on Member's county and season schedule)

**Attachments:** N/A

<b>Revision Log</b>	<b>Date</b>
Complete reformatting of document to remove Centene criteria and preface SHP criteria and wording, inserted criteria consistent to 2015-2016 Texas Vendor Drug Criteria, inserted 2015-2016 Synagis PA fax, 2015-2016 Season Schedule	9/2015
Updated season schedule, PA form and changed season dates to reflect 2016-2017 Synagis season. Added language to allow acceptance of TDI general PA form.	09/2016
Updated name of P&P, season schedule, PA form and changed season dates to reflect 2017-2018 Synagis season.	09/2017
Updated name of P&P to include reference to 2018-2019 season and made same necessary updates throughout the document. Clinical criteria step 19: Removed bronchodilator therapy. Updated Policy section to include reference to Texas Department of Insurance (TDI) standard PA form. Added "The Provider is encouraged to fill out the Synagis Addendum if the TDI PA form is used. This addendum supports the clinically necessary information Superior needs to properly review the PA request."	09/2018
Added "systemic" to line 19. Removed "Justin M. Weiss, Sr. V.P., Pharmacy Operations" and added "Karen Tadlock, Sr Director, Clinical Pharmacy Services"	12/11/2018

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Updated name of P&P to include reference to 2019-2020 season and made same necessary updates throughout the document.	9/5/2019
Added 'and will require cardiac surgery' to question 8 in criteria	10/24/2019
CHIP is added as a covered benefit through medical and not pharmacy benefits.	11/27/2019
Reformatting only	2/20/2020

### ***POLICY AND PROCEDURE APPROVAL***

Karen Tadlock, Sr Director, Clinical Pharmacy Services      Approval on file

Dr. David Harmon, Sr. V.P., Chief Medical Officer      Approval on file

Pharmacy & Therapeutics Committee:      Approval on file

*NOTE: The electronic approval retained in RSA Archer, Centene's P&P management software, is considered equivalent to a physical signature.*