

Georgia Medicaid Fee-For-Service Synagis[®] Policy for RSV Season 2020 – 2021

***June 2021 Update to Synagis[®] Policy for RSV Season 2020 – 2021:** In light of the recent health advisory by the Centers for Disease Control and Prevention (CDC) highlighting increased interseasonal Respiratory Syncytial Virus (RSV) levels across parts of the Southern United States, including Georgia, the Georgia Department of Community Health (GDCH) will review Synagis[®] (palivizumab) requests on a case-by-case basis outside of the typical RSV season to ensure that an appropriate pathway to coverage is available for eligible patients. GDCH will monitor and utilize RSV surveillance data reported by the CDC and the Georgia Department of Public Health (GDPH) to approve Synagis[®] (palivizumab) doses on a monthly basis for eligible patients until RSV levels are below threshold. To request coverage through Pharmacy Services, please fax a letter of medical necessity and the Synagis[®] PA Request form to OptumRx at 1-877-239-4565. The Synagis[®] PA Request Form can be located at <http://dch.georgia.gov/prior-authorization-process-and-criteria>.

The Georgia Department of Community Health (GDCH) provides this policy for Synagis[®] (palivizumab) prophylaxis for its Fee-For-Service (FFS) members during the 2020-2021 respiratory syncytial virus (RSV) season. The policy is centered on the recommendations by the American Academy of Pediatrics (AAP) and the Georgia Chapter of the AAP (GAAAP). Based on the review of data on the seasonality of RSV, palivizumab pharmacokinetics, changing incidence of bronchiolitis hospitalizations, effect of gestational age and other risk factors on RSV hospitalization rates, mortality of children hospitalized with RSV infection, effect of wheezing, and palivizumab-resistant RSV isolates, the AAP/GAAAP recommendations are driven by the limited clinical benefit derived from palivizumab prophylaxis. The GDCH policy is as follows:

- According to AAP/GAAAP, in general, up to five doses are sufficient to provide protection throughout the RSV season since five monthly doses will provide more than 6 months (>24 weeks) of serum concentrations. A maximum of up to 5 doses will be allowed for the following members:
 - Preterm infants <29 weeks' gestation who are <12 months of age.
 - Preterm infants <12 months of age with chronic lung disease (CLD) of prematurity (<32 weeks' gestation) who required >21% oxygen therapy during the first 28 days of life. Prophylaxis will be allowed for these members during the 2nd year of life if they required medical support during the 6-month period before the RSV season.
 - Infants <12 months of age with hemodynamically significant congenital heart disease (CHD) who are acyanotic receiving medication to control congestive heart failure (CHF) and will require cardiac surgical procedures or have moderate to severe pulmonary hypertension or have cyanotic heart defects and the decision regarding RSV prophylaxis was made in consultation with a pediatric cardiologist.
 - Infants <12 months of age with pulmonary abnormality or neuromuscular disease that impairs ability to clear secretions from the upper airways.
 - Children <24 months of age who are profoundly immunocompromised.
 - Children <24 months of age with cystic fibrosis.
- Dosing will not be allowed for infants with active infection or history of infection during the current season.
- High-risk infants discharged from the hospital in February should receive a February and a March dose. High-risk infants discharged from the hospital in March should receive a March dose. High-risk infants born during the RSV season should receive a dose in the hospital 48-72 hours prior to discharge.
- Only prescribers or prescriber offices are allowed to submit requests for Synagis[®]. Stamped or copied signatures will not be accepted.

Based on RSV surveillance data, the RSV season in Georgia is typically October through March. Thus, GDCH will allow RSV prophylaxis therapy of up to 5 doses with palivizumab beginning October 1, 2020 and ending March 3, 2021 based on AAP/GAAAP recommendations. If the season extends into March, dosing exceptions past March 3rd through March 31st will be allowed for high-risk infants discharged from the hospital in February as well as in March who do not receive the March dose in the hospital. Please see the table below for the maximum number of palivizumab doses. We will continuously monitor the start and end of the 2020-2021 RSV season. Please check back for any changes or updates.

1. American Academy of Pediatrics. Policy Statement: Updated guidelines for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics* 2014;134(2):415-20. [Reaffirmed 2019]
2. Georgia Chapter American Academy of Pediatrics. Blastfax: Guidance for Palivizumab Prophylaxis among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. Available at www.gaaap.org.
3. Georgia Division of Public Health. Respiratory Syncytial Virus (RSV) Surveillance in Georgia. Available at <http://dph.georgia.gov/respiratory-syncytial-virus-rsv>.
4. Centers for Disease Control and Prevention. Respiratory Syncytial Virus Surveillance. Available at <http://www.cdc.gov/surveillance/nrevss/rsv/state.html>.



For Georgia Medicaid FFS members, Synagis® prior authorizations (PA) through Pharmacy Services must be faxed to OptumRx at 1-888-491-9742 using the Synagis® PA Request Form located at <http://dch.georgia.gov/prior-authorization-process-and-criteria>. For Synagis® prior authorizations through Physician Services, please go to the Registered User portion of the Georgia Health Partnership portal at <https://www.mmis.georgia.gov>.

Sincerely,
Georgia Department of Community Health

Maximum Number of Prophylaxis Palivizumab Doses for Preterm Infants RSV Season 2020-2021

Month of First Dose ^a	Maximum Number of Doses ^b				
	<29 weeks' gestation and <12 months of age at time of first injection	<12 months of age with CLD of prematurity (<32 weeks' gestation) who required >21% oxygen therapy during first 28 days of life and <24 months of age with CLD of prematurity (<32 weeks' gestation) who required >21% oxygen therapy during first 28 days of life and continue to require medical support within 6 months at time of first injection	<12 months of age with hemodynamically significant CHD who are acyanotic receiving medication for CHF and will require cardiac surgery or who have moderate to severe hypertension or have cyanotic heart defects in consultation with a pediatric cardiologist at time of first injection	<12 months of age with pulmonary abnormality or neuromuscular disease that impairs ability to clear secretions from upper airways at time of first injection	<24 months of age who are profoundly immunocompromised or have cystic fibrosis at time of first injection
October 2020	5	5	5	5	5
November 2020	4	4	4	4	4
December 2020	3	3	3	3	3
January 2021	2	2	2	2	2
February 2021 ^c	2	2	2	2	2
March 2021 ^d	1	1	1	1	1

Adapted from the recommendations by the American Academy of Pediatrics (AAP) and the Georgia Chapter of the AAP.

^aMonth of first dose during the current season from October 1, 2020-March 3, 2021. If the season extends into March, dosing exceptions past March 3rd through March 31st will be allowed for high-risk infants discharged from the hospital in February as well as in March who do not receive the March dose in the hospital.

^bIf the first dose during the current season was given at the hospital, subtract 1 dose from the number of maximum doses allowed based on when Synagis was started during the current season.

^cApplies to high-risk infants discharged from the hospital in February only during the current season: High-risk infants discharged from the hospital in February should receive a February dose and a March dose. The February dose should be received in the hospital 48-72 hours prior to discharge.

^dApplies to high-risk infants discharged from the hospital in March only during the current season: High-risk infants discharged from the hospital in March should receive a March dose. The March dose should be received in the hospital 48-72 hours prior to discharge.

1. American Academy of Pediatrics. Policy Statement: Updated guidelines for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics* 2014;134(2):415-20. [Reaffirmed 2019]
2. Georgia Chapter American Academy of Pediatrics. Blastfax: Guidance for Palivizumab Prophylaxis among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. Available at www.gaaap.org.
3. Georgia Division of Public Health. Respiratory Syncytial Virus (RSV) Surveillance in Georgia. Available at <http://dph.georgia.gov/respiratory-syncytial-virus-rsv>.
4. Centers for Disease Control and Prevention. Respiratory Syncytial Virus Surveillance. Available at <http://www.cdc.gov/surveillance/nrevss/rsv/state.html>.