PROVIDER POLICIES & PROCEDURES

PALIVIZUMAB (SYNAGIS®)

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for Palivizumab (Synagis®). By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

Certain infants and young children should be strongly considered as candidates for Palivizumab (Synagis®) for respiratory syncytial virus (RSV) infection prophylaxis. Recommendations for the use of Palivizumab for those considered at particular risk of RSV infection-related hospitalization are periodically published by the American Academy of Pediatrics.

CLINICAL GUIDELINE

Coverage guidelines for the use of Palivizumab will be made in accordance with the DSS definition of Medical Necessity and in line with published recommendations of the American Academy of Pediatrics. The following criteria are guidelines *only*. Coverage guidelines are based on an assessment of the individual and his or her unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

Palivizumab may be considered medically necessary for a defined set of infants and young children. Use of Palivizumab is generally considered medically necessary **during the first year of life** when the following criteria are met:

1. The infant has not received Beyfortus™ (nirsevimab-alip) for the prevention of RSV during this RSV season; **AND**
2. Infant born before 29 weeks, 0 days gestation; **OR**
3. Preterm infant born before 32 weeks, 0 days gestation with chronic lung disease of prematurity defined as a requirement for greater than 21% oxygen for at least 28 days after birth; **OR**
4. Certain infants with hemodynamically significant heart disease.

   Note: For infants with asymptomatic heart disease, a consultation with a cardiologist for decisions about prophylaxis is required.

Use of Palivizumab is typically not recommended during the second year of life except for preterm infants born before 32 weeks, 0 days' gestation who required at least 28 days of supplemental oxygen after birth and who continued to require medical intervention (supplemental oxygen, systemic corticosteroids or diuretic therapy) during the 6-months prior to the start of the second RSV season.

Other possible candidates for Palivizumab are:

1. Those children less than 12 months of age who have a pulmonary abnormality or a neuromuscular disease that impairs the ability to clear secretions; **OR**

2. Those children who will be profoundly immunocompromised and are less than 24 months of age.

Note: Monthly prophylaxis should be discontinued in any child who experiences a breakthrough RSV hospitalization.

Providers typically administer a maximum of 5 consecutive doses of Palivizumab to infants who qualify for prophylaxis in the first year of life.

Note: See complete American Academy of Pediatrics (AAP) recommendations (reference noted below) for detailed information and discussion of indications for Palivizumab.

NOTE: EPSDT Special Provision
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE
Prior authorization of Palivizumab is required. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

The following information is needed to review requests for Palivizumab:

1. Fully completed State of Connecticut, Department of Social Services HUSKY Health Program Palivizumab (Synagis®) Request form (to include physician's order and signature);
2. Clinical information supporting the medical necessity of the treatment; and
3. Other information as requested.

Authorizations for Palivizumab typically expire on 4/30/2024. Requests to extend the end date beyond 4/30/2024 will be reviewed on a case-by-case basis.

Requesting Authorization:
Requests for the prior authorization of Palivizumab must be submitted by the ordering physician and faxed to the number listed on the Palivizumab (Synagis®) Request Form. Questions regarding this form should be directed to the HUSKY Health Program Utilization Management Department at 1.800.440.5071 (select option for medical authorizations).

EFFECTIVE DATE
This Policy is effective for prior authorization requests for Palivizumab treatment for individuals covered under the HUSKY Health Program on October 1, 2012.

LIMITATIONS
Not Applicable

CODE:

Code	Definition
90378	Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, mg, each

DEFINITIONS

1. **Current Procedural Terminology (CPT):** The most recent edition of a listing, published by the American Medical Association, of descriptive terms and identifying codes for reporting medical services performed by providers.
2. **HUSKY A**: Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
3. **HUSKY B**: Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
4. **HUSKY C**: Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
5. **HUSKY D**: Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
6. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
7. **HUSKY Limited Benefit Program or HUSKY, LBP**: Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
8. **Medically Necessary or Medical Necessity**: (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B)recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.
9. **Prior Authorization**: A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

ADDITIONAL RESOURCES AND REFERENCES:

1. American Academy of Pediatrics (AAP) Policy Statement. Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. Pediatrics. 2014 Aug; 134:415-420. Accessed July 29, 2014.
2. American Academy of Pediatrics. Respiratory Syncytial Virus. In: eds. *Red Book: 2021-2024 Report of the Committee of Infectious Diseases.* American Academy of Pediatrics; 2021; 628-636
3. BEYFORTUS [Package Insert]. Swiftwater, PA: Sanofi Pasteur, Inc.; July 2023. Available at: https://products.sanofi.us/beyfortus/beyfortus.pdf
4. Caserta MT, et al, Palivizumab Prophylaxis in Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. Pediatrics. 2023 June; 152 (1).
5. DSS Provider Bulletin 2009-11: New Prior Authorization Requirements for Synagis®, dated October 2009

PUBLICATION HISTORY

Status	Date	Action Taken
Original publication	October 2012	
Reviewed	December 2013	Clinical Quality Sub-Committee Review. Reference updated. These changes approved at the December 16, 2013 Clinical Quality Sub-Committee meeting.
Reviewed	August 2014	CHNCT Medical Management review. Clinical Guideline section updated to reflect revised guidelines from the American Academy of Pediatrics (AAP) outlined in the policy statement published in the August 2014 issue of Pediatrics. These changes approved at the September 14, 2014 Clinical Quality Sub-Committee meeting.
Reviewed	May 2015	CHNCT Medical Management Review. Updated Reference for AMA CPT Manual to 2015 version. Updated timeframe for upcoming RSV season to 2015-2016. Updated phone and fax numbers.
Updated	August 2015	Updated definitions for HUSKY A, B, C and D at request of DSS.
Updated	March 2016	Updates to language in introductory paragraph pertaining to purpose of policy. Updates to Clinical Guideline section pertaining to definition of Medical Necessity. Updates throughout policy to reflect importance of person-centeredness when reviewing requests for Palivizumab. Updates approved at the March 21, 2016 Clinical Quality Subcommittee meeting. Updates approved by DSS on June 15, 2016.
Updated	August 2016	Updates to dates within policy to reflect current season. Updates approved by DSS on August 17, 2016.

Updated	July 2017	Updates to dates within policy to reflect current season. Approved by Medical Policy Committee on July 26, 2017. Approved by Clinical Quality Subcommittee on September 21, 2017. Approved by DSS on August 1, 2017.
Update	July 2018	Updated reference for AMA CPT Manual to 2018 version. Updated timeframe for upcoming RSV season to 2018-2019. Changes approved at the July 25, 2018 Medical Policy Review Committee meeting. Approved by the CHNCT Clinical Quality Subcommittee on September 17, 2018. Approved by DSS on September 19, 2018.
Update	July 2019	Updated reference for AMA CPT Manual to 2019 version. Updated timeframe for upcoming RSV season to 2019-2020. Changes approved at the July 24, 2019 Medical Reviewer Meeting. Approved by the CHNCT Clinical Quality Subcommittee on September 16, 2019. Approved by DSS on September 19, 2019.
Update	August 2020	Updated reference for AMA CPT Manual to 2020 version. Updated time frame. Changed chronic corticosteroid to systemic corticosteroid. Extended authorization expiration date to 4/30/2021. Removed statement regarding infants born during RSV season requiring fewer doses. Changes approved at the August 12, 2020 Medical Reviewer meeting. Changes approved by the CHNCT Clinical Quality Subcommittee on September 21, 2020. Approved by DSS on October 7, 2020.
Update	September 2021	Removed reference to “RSV season”. Added word “typically” to language related to maximum of 5 doses and authorization end date of 4/30/2021. Updated dates to 2021-2022. Updated reference section to include AAP Red Book citation. Updated reference for AMA CPT Manual to 2021 version. Changes approved at the August 11, 2021 CHNCT Medical Reviewer meeting. Changes approved by the CHNCT Clinical Quality Subcommittee on September 20, 2021. Approved by DSS on September 30, 2021.
Update	September 2022	Added “as a requirement for” to criteria #2. Changed “5 monthly doses to 5 consecutive doses”. Update to dates for upcoming RSV season. Changes approved at the August 10, 2022 CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on September 19, 2022. Approved by DSS on September 28, 2022.
Update	September 2023	Changed the verbiage in the note below criteria #4 to read “For infants with asymptomatic heart disease, a consultation with a cardiologist for decisions about prophylaxis is required.” Added “during the 6-months prior to the start of the second RSV season” to the section regarding use in the second year of life. Added statement regarding Beyfortus, Updated dates within policy to reflect current RSV season. Added additional references. Changes approved at the August 9, 2023 CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on September 18, 2023. Approved by DSS on October 2, 2023.