Prior Authorization Required From CHN

Eteplirsen (Exondys®) Guidelines

Coverage guidelines for Eteplirsen are made in accordance with the Department of Social Services (DSS) definition of Medical Necessity, as established by state law. The following factors are guidelines *only.* Coverage determinations 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.

Payment will be considered for patients when the following guidelines are met:

- Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with mutation amenable to exon 51 skipping confirmed by genetic testing.
  (*NOTE: physician must provide results of genetic testing*)

- Must be prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy.

- Patient is currently ambulatory and able to achieve an average distance of at least 180 meters while walking independently over six minutes.
  (NOTE: physician must attach a baseline 6 – Minute Walk Test [6MWT])

- Patient is currently stable on oral corticosteroid regimen for at least 6 months.

- Must be dosed on FDA approved dosing: 30mg/kg once weekly.

If guidelines for coverage are met, initial authorization will be given for 6 months *only*.

Requests for continuation of therapy will be considered at 6 month intervals when the following are met:

- Patient has demonstrated a response to therapy as evidenced by remaining ambulatory (able to walk with or without assistance, not wheelchair dependent).

- An updated 6MWT must be provided documenting the patient is able to achieve a distance of at least 180 meters.

PA requests for coverage of Eteplirsen must be submitted by the prescriber in the form of a letter of medical necessity to the Department's Medical Director. Letters of medical necessity should be faxed to (860) 424-4822 with the required documentation outlined in the Eteplirsen Coverage Guidelines.

Prior Authorization Required From CHN

Nusinersen (Spinraza®) Guidelines

Coverage guidelines for Nusinersen are made in accordance with the Department of Social Services (DSS) definition of Medical Necessity, as established by state law.

The following factors are guidelines *only.* Coverage determinations 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 following factors will be considered in the Department's prior authorization decision

I. Type 1 Patients

SMA Type 1 patients with symptom onset at < 6 months of age are eligible for treatment if the following conditions are met:

1) The Diagnosis of SMA1 must be made by a Neurologist with expertise in diagnosing Spinal Muscular Atrophy. For purposes of this guideline, "Neurologist" refers to a Board Certified Neurologist, preferably specializing in pediatric neurology, **AND**

- Genetic testing confirming **both**:
  - Mutation/deletion in chromosome 5q with
  - Homozygous gene deletion/mutation of exon 7 at 5q13 *or* compound heterozygous mutation: deletion SMN1 exon 7 allele1 and mutation of SMN1 allele 2

- And at least two copies of SMN2; AND

2) Documentation that the patient is either **not on any artificial ventilation,** or if on artificial ventilation or other mechanical respiratory support prior to **Nusinersen,** the type, duration and degree of ventilator support in a 24 hour period must be documented; AND

3) Submission of medical records documenting a **baseline motor exam by a physician (Neurologist or PMR (Physical Medicine & Rehabilitation Specialist)) or physical therapist specializing in SMA motor exam evaluations and supervised by Neurologist or PMR physician)** experienced in treating SMA and utilizing at least one of the following exam instruments (based on patient's age), to establish this baseline motor ability**:**

- o Hammersmith Infant Neurological Exam (HINE)
- o Hammersmith Functional Motor Scale Expanded (HFMSE)
- o Upper Limb Module Test (non-ambulatory)
- o Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND); AND

4) **Nusinersen** must be **ordered by a Neurologist** experienced in treating SMA.
Initial approval of Nusinersen will be for 5 doses ONLY to be given in accordance with the current Nusinersen FDA label instructions**.** Protocol: loading doses at day 0 (dose 1), day 14 (dose 2), day 28 (dose 3), 30 days post day 28 (dose 4) and 4 months after that fourth dose (dose 5).

Prior Authorization Required From CHN

Guidelines for subsequent doses of Nusinersen:

After the 5 loading doses are completed, patient must be **re-evaluated using the same motor exam test done to establish baseline motor ability** unless it is determined that the original exam instrument is no longer age- appropriate. This re-examination must be done, whenever possible, by the same examiner as baseline exam. If this is not possible, then the re-examination must be done by another physician (Neurologist or PMR who is experienced in treating SMA or a physical therapist specializing in SMA motor exam evaluations and supervised by Neurologist or PMR physician).

• Nusinersen will be authorized for an additional 6 months if a patient is determined to be a responder by
demonstrating an **improved motor ability** in repeat motor testing after the 5th loading dose.

To be classified as a responder, the patient should receive the following score(s) on the motor

test used: HINE: a 2 point increase (or max score of 4) in ability to kick (consistent with

improvement by at
least 2 milestones) or a 1 point increase in motor milestones of head control, rolling, sitting, crawling, standing or walking (consistent with improvement by at least 1 milestone). Responder needs to exhibit improvement in more categories of motor milestones than worsening.

HFMSE: (Scored as 0, 1 or 2 with maximum of 40). Improvement of at least a 3 point increase in
score from pretreatment baseline

ULM: Improvement of at least 2 point increase in score from pretreatment baseline

CHOP INTEND: Improvement of at least 4 point increase in score from pretreatment baseline

• **Renewal authorization,** will be for 6 months. Nusinersen administration will follow the current FDA Nusinersen labelling for maintenance dosing protocol of every 4 months

• **Repeat motor testing** must be done at 6 month intervals and must show additional motor improvement or maintenance of the previously demonstrated motor improvement. If a patient becomes dependent on mechanical ventilator (defined as requiring mechanical ventilation for > 21 days) while on Nusinersen, then the Department will no longer authorize payment of Nusinersen for that patient.

The 6 month periodic re-examination must be done by the same examiner as the baseline exam whenever possible. If this is not possible, it must be conducted by another physician (Neurologist or PMR) who is experienced in treating SMA who must use the same exam instrument unless it is determined that original exam instrument is no longer age appropriate.

II. ***Other SMA Types*** **- Patients with other SMA Types are eligible for treatment if the following conditions are met:**

1) A diagnosis of SMA must be made by a Neurologist with expertise in diagnosing Spinal Muscular Atrophy; AND

2) All of the documentation listed above will be required; AND

3) **In addition,** documentation must be provided demonstrating in the opinion of the treating neurologist, why a patient should be considered for administration of Nusinersen given the research demonstrating efficacy is limited and equivocal.

Prior Authorization Required From CHN

If approved for a patient with a non-Type 1 SMA diagnosis, the dosage and renewal guidelines described above will also apply.

- Pharmacy Prior Authorization Submission Process: PA requests for coverage of Nusinersen must be submitted by the prescriber in the form of a letter of medical necessity to DSS' Medical Director. Letters of medical necessity must be faxed to (860) 424-4822 with the required documentation outlined in the Nusinersen Coverage Guidelines. Outpatient Hospital

- Prior Authorization Submission Process: Effective November 1, 2017 and forward, outpatient hospitals buying and billing for Spinraza must utilize a separate PA process identified below. Outpatient hospitals must fax a completed Spinraza PA Request Form along with the required documentation to Community Health Network of CT, Inc. (CHNCT) at (203) 265-3994.

Prior Authorization Required From CHN

Palivizumab (Synagis®) Guidelines

Certain pediatric patients should be strongly considered as candidates for palivizumab (Synagis®) for respiratory syncytial virus (RSV) infection prophylaxis. Recently published (August 2014) American Academy of Pediatrics recommendations[1] for the use of palivizumab offers the following guidelines to identify those infants who may particularly benefit from monthly doses of palivizumab throughout the duration of the RSV season, which in Connecticut is typically November 1 through March 31.

Note: The following criteria are guidelines *only*. Determinations of coverage will be made in accordance with the Department of Social Services (DSS) Definition of Medical Necessity and are based on an individual assessment of the member and his or her clinical needs.

First Year of Life:

1. Infants born **before 29 weeks, 0 days'** gestation.
2. Preterm infants born **before 32 weeks, 0 days'** gestation with chronic lung disease of prematurity defined as greater than 21% oxygen for at least 28 days after birth.
3. Certain infants with hemodynamically significant heart disease. (Note: consultation with a cardiologist for decisions about prophylaxis is recommended for patients with cyanotic heart disease).

Second Year of Life:

Palivizumab prophylaxis is **not recommended in 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 continue to require medical intervention (supplemental oxygen, chronic corticosteroid or diuretic therapy).

Other Possible Candidates:

1. Children **younger than 24 months of age** who will be profoundly immunocompromised during the RSV season may be considered for prophylaxis.
2. Children with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways may be considered for prophylaxis in the **first year of life.**

NOTE: Monthly prophylaxis should be discontinued in any child who experiences a breakthrough RSV hospitalization. As noted in the current AAP recommendations, "**Clinicians may administer up to a maximum of five monthly doses of Palivizumab during the RSV season to infants who qualify for prophylaxis in the first year of life (including those in Florida). Qualifying infants born during the RSV season will require fewer doses.** For example, infants born in January would receive their last dose in March." [1]

Outpatient hospitals must fax a completed PA request form along with supporting clinical information to Community Health Network of Connecticut, Inc. (CHNCT) at 203-774-0549.

For questions regarding the prior authorization process, please contact CHNCT at 1-800-440-5071, Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m.

Prior Authorization Required From CHN

Tisagenlecleucel (Kymriah®) Guidelines

Coverage decisions for the use of Kymriah will be made in accordance with the DSS definition of Medical Necessity. The following criteria are guidelines *only*. Coverage decisions are based on an assessment of the individual and their 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:

I. Kymriah will be considered medically necessary based on the FDA approved indication for the treatment of B-cell precursor acute lymphoblastic leukemia (ALL) that meet ALL of the following criteria:
   A. The disease is refractory or in second or later relapse defined as ONE of the following:
      1. Second or greater bone marrow (BM) relapse OR
      2. Any BM relapse after allogeneic stem cell transplantation (SCT) OR
      3. Primary refractory (not achieving a complete response after 2 cycles of standard chemotherapy or chemorefractory (not achieving a complete response after 1 cycle of standard chemotherapy for relapsed disease) OR
      4. Individuals with Philadelphia chromosome (Ph) positive disease have a contraindication, intolerance, or have failed two prior lines of tyrosine kinase inhibitor (TKI) therapy OR
      5. The individual is not eligible for allogeneic SCT

      AND
   B. The individual has confirmed CD19 tumor expression

      AND
   C. The individual is ≤ 25 years of age

      AND
   D. The individual has not previously been treated with gene therapy or Kymriah

      AND
   E. The individual does not have:
      1. Unresolved serious adverse reactions from preceding chemotherapies (including pulmonary toxicity, cardiac toxicity, or hypotension)
      2. Active infection (including Hepatitis B, Hepatitis C, or HIV infection)
      3. An inflammatory disorder
      4. Active graft versus host disease (GVHD)
      5. Worsening leukemia burden, including active central nervous system (CNS) malignancy involvement

      AND
   F. The individual is not at risk for Hepatitis B or the individual is at risk for Hepatitis B and Hepatitis B has been ruled out or treatment for Hepatitis B has been initiated

      AND
   G. The individual has been screened for Hepatitis B, Hepatitis C and HIV before collection of cells for manufacturing

      AND
   H. Prophylaxis for infection has been followed according to local guidelines

      AND
   I. The individual has not received live vaccines within 2 weeks prior to the start of lymphodepleting chemotherapy and will not receive live vaccines until immune recovery following Kymriah treatment

      AND
   J. The individual has received or will receive lymphodepleting chemotherapy [Fludarabine (30 mg/m^2 intravenous daily for 4 days) and cyclophosphamide (500 mg/ m^2 intravenous daily for 2 days starting with the first dose of Fludarabine)] within two weeks preceding Kymriah infusion

      AND
   K. The dose does not exceed one of the following:

1. Weight less than or equal to 50 kg: 0.2 to 5.0 X 10^6 chimeric antigen receptor (CAR) – positive viable T-cells per kg of body weight intravenously
2. Weight greater than 50 kg: 0.1 to 2.5 X 10^8 CAR-positive viable T-cells intravenously

AND

L. The prescriber agrees to monitor the individual for signs and symptoms of cytokine release syndrome (CRS) and administer tocilizumab if needed

AND

M. The prescriber agrees to monitor the patient for signs and symptoms of neurological toxicities

AND

N. The healthcare facility has enrolled in the Kymriah REMS program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities

II. Kymriah is typically considered investigational and therefore not medically necessary for all other indications. Again, however, if an individual does not meet these criteria, an assessment of the individual's unique clinical needs will also be conducted.

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 Kymriah 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 Kymriah:

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

Requesting Authorization
Requests for the prior authorization of Kymriah must be submitted by the ordering physician and faxed to the number listed on the 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).

Initial Authorization
If approved, authorization will be given for 1 dose only.

Reauthorization
Not applicable

EFFECTIVE DATE
This Policy for the prior authorization of Kymriah for individuals covered under the HUSKY Health Program is effective April 1, 2018.

Prior Authorization Required From CHN

LIMITATIONS

One time dose per lifetime

CODE:

Code	Definition
Q2040	Tisagenlecleucel, up to 250 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion

DEFINITIONS

1. **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.
2. **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.
3. **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.
4. **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).
5. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
6. **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.
7. **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.
8. **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.

Prior Authorization Required From CHN

ADDITIONAL RESOURCES AND REFERENCES:

Hartmann J, Schüler-Lenz M, Bondanza A, Buchholz CJ. Clinical development of CAR T cells - challenges and opportunities in translating innovative treatment concepts. EMBO Mol Med. 2017 August 1. http://embomolmed.embopress.org/content/early/2017/07/31/emmm.201607485.long. Accessed on December 18, 2017.

Kymriah [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp.; August 2017.

National Comprehensive Cancer Network. Acute Lymphoblastic leukemia. Version 5.2017 – October 2017. Available at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed on December 19, 2017.

Novartis Pharmaceuticals. Determine efficacy and safety of CTL019 in pediatric patients with relapsed and refractory B-cell ALL (ELIANA). NCT 02435849. Updated July 28, 2017. Available at: https://clinicaltrials.gov/ct2/show/NCT02435849?term=ELIANA&rank=1. Accessed on December 19, 2017.

U.S. Food and Drug Administration. Approved Risk Evaluation and Mitigation Strategies (REMS). Updated 08/30/2017. Available at: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=indvremsdetails.page&rems=368. Accessed on December 20, 2017.

UpToDate. Treatment of relapsed or refractory acute lymphoblastic leukemia in adults. Last updated 11/21/2017.

PUBLICATION HISTORY

Status	Date	Action Taken
Original publication	March 2018	Approved by CHNCT Medical Policy Review Committee on January 24, 2018. Approved by DSS on March 13, 2018. Approved by CHNCT Clinical Quality Subcommittee on March 20, 2018.

Prior Authorization Required From CHN

Voretigene Neparvovec-rzyl (Luxturna®) Guidelines

Coverage decisions for the use of Luxturna will be made in accordance with the DSS definition of Medical Necessity. The following criteria are guidelines *only*. Coverage decisions are based on an assessment of the individual and their 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:

III. Luxturna will be considered medically necessary based on the FDA approved indication of confirmed biallelic RPE65 mutation-associated retinal dystrophy when ALL of the following criteria are met:

O. The individual has a diagnosis, confirmed by genetic testing, of biallelic RPE65 mutation-associated retinal dystrophy
AND

P. The individual has viable retinal cells as determined by the treating physician
AND

Q. The individual is ≥ 12 months of age (Safety and efficacy has not been established in individuals under 12 months of age)
AND

R. The individual is < 65 years of age (Safety and efficacy has not been established in individuals 65 years of age and older)
AND

S. Dose administered will be 1.5×10^{11} vector genomes per eye
AND

T. Luxturna will be administered via subretinal injection to each eye on separate days within a close interval but no fewer than 6 days apart
AND

U. The injection will not be administered in the immediate vicinity of the fovea
AND

V. The individual will receive systemic oral corticosteroids following FDA recommendations
AND

W. The prescriber agrees to monitor the individual for signs of infection, visual disturbances, retinal abnormalities and increased intraocular pressure post injection
AND

X. The prescriber agrees to instruct the individual to avoid air travel, travel to high elevations and scuba diving until the air bubble formed following administration of Luxturna has completely dissipated from the eye.
Note: The prescriber must verify dissipation of the air bubble through ophthalmic examination

IV. Luxturna is typically considered investigational and therefore not medically necessary for all other indications. Again, however, if an individual does not meet these criteria, an assessment of the individual's unique clinical needs will also be conducted.

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].

Prior Authorization Required From CHN

PROCEDURE
Prior authorization of Luxturna 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 Luxturna:

4. Fully completed State of Connecticut, Department of Social Services HUSKY Health Program Luxturna Prior Authorization Request form (to include physician's order and signature);
5. Genetic testing results;
6. Clinical information supporting the medical necessity of the treatment as outlined above; and
7. Other information as requested.

Requesting Authorization
Requests for the prior authorization of Luxturna must be submitted by the ordering physician and faxed to the number listed on the 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).

Initial Authorization
If approved, authorization will be given for 1 dose per eye

Reauthorization
Not applicable

EFFECTIVE DATE
This Policy for the prior authorization of Luxturna for individuals covered under the HUSKY Health Program is effective April 1, 2018.

LIMITATIONS
One time dose each eye per lifetime

CODES:

Code	Definition
J3590	Unclassified biologics
C9399*****	Unclassified drugs or biologicals

*****Use for outpatient hospital billing only

DEFINITIONS

7. **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.
8. **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.
9. **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.
10. **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).
11. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.

12. **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.
13. **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.
14. **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:

- Luxturna [package insert].Philadelphia, PA: Spark Therapeutics, Inc.; 2017
- Food and Drug Administration (FDA) News Release: FDA approves novel gene therapy to treat patients with a rare form of inherited vision loss. December 19, 2017. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm589467.htm. Accessed on December 27, 2017.

PUBLICATION HISTORY

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