MetroPlus Health Plan

Policy and Procedure

Title: Kymriah	**Division: Medical Management** **Department: Utilization Management**
Approval Date: 3/30/18	**LOB: Medicaid, FHP, HIV SNP, CHP, MetroPlus Gold, Market Plus, Essential, HARP**
Effective Date: 3/30/18	**Policy Number: UM-MP219**
Review Date: 3/30/19	**Cross Reference Number:**
Retired Date:	**Page 1 of 3**

1. POLICY DESCRIPTION:

Kymriah (Tisagenlecleucel) is a chimeric antigen receptor T Cell (CAR-T) which reprograms a patient's own T cells to identify and eliminate CD19 expressing malignant and normal cells. Upon binding to CD-19 expressing cells, the CAR promotes T-cell expansion, activation and target cell elimination.

Kymriah is indicated as a single agent therapy for refractory or relapsed B-cell precursor acute lymphoblastic leukemia in members 25 years of age or younger. Repeat administration is considered experimental and investigational.

All other uses for Kymriah are considered experimental and investigational.

2. RESPONSIBLE PARTIES:

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claims Department, Provider Contracting.

3. POLICY:

Kymriah will be considered medically necessary when the following conditions of coverage have been met:

a. Member is 3-25 years of age
b. Member is diagnosed with refractory or relapsed B-cell precursor acute lymphoblastic leukemia (ALL)
    i. The disease is refractory or in second or later relapse defined as one of the following:
        1. Second or later bone marrow relapse
        2. Any bone marrow relapse after allogenic stem cell transplantation
        3. Failure of 2 lines of tyrosine kinase inhibitor therapy (TKI) for patients with Philadelphia chromosome positive disease
        4. Failure of 2 cycles of a standard chemotherapy regimen or chemorefractory as defined by not achieving a CR after 1 standard chemotherapy for relapsed leukemia
        5. Ineligible for allogeneic SCT
c. This member has not previously been treated with CAR-T therapy
d. The member has documentation of CD19 positive disease

e. Performance score on Karnofsky or Lansky Scale is greater than or equal to 50%.
f. Life expectancy > 12 weeks
g. FDA approved dosing is administered
h. Member does not have an active infection or inflammatory disorder
i. Patient is screened for HBV, HCV, and HIV in accordance with clinical guidelines prior to collection of cells for manufacturing.

4. APPLICABLE PROCEDURE CODES

CPT Code	Description
Q2040	Tisagenlecleucel, up to 250 million CAR-positive viable T cells, including leukapheresis and dose preparation procedure, per infusion

References

1. Kymriah [Product Information], Novartis Pharmaceuticals Corporation, East Hanover, NJ; August 2017. Available at: https://www.fda.gov/downloads/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/UCM573941.pdf.
2. Porter DL, Hwang WT, Frey NV, et al. Chimeric antigen receptor T cells persist and induce sustained remissions in relapsed refractory chronic lymphocytic leukemia. Sci Transl Med. 2015 Sep 2;7(303):303ra139. doi: 10.1126/scitranslmed.aac5415

REVISION LOG:

REVISIONS	DATE
Creation date	

Approved:	Date:	Approved:	Date:

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Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and website links are accurate at time of publication.