I. Medication Description

Polatuzumab vedotin-piiq is a CD79b-directed antibody-drug conjugate with activity against dividing B cells. The small molecule, MMAE, is an anti-mitotic agent covalently attached to the antibody via a cleavable linker. The monoclonal antibody binds to CD79b, a B-cell specific surface protein, which is a component of the B-cell receptor. Upon binding CD79b, polatuzumab vedotin-piiq is internalized, and the linker is cleaved by lysosomal proteases to enable intracellular delivery of MMAE. MMAE binds to microtubules and kills dividing cells by inhibiting cell division and inducing apoptosis.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Polivy is available when the following criteria have been met:

- Member is at least 18 years of age AND
- The medication is prescribed by a hematologist/oncologist AND
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

Coverage is available for a quantity sufficient to allow for FDA-approved dosing.

V. Coverage Duration

Coverage is provided for 6 months initially and may be renewed in 6 month intervals.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression AND
- Absence of unacceptable toxicity from the drug
## VII. Billing/Coding Information

- Available as 140mg single dose vial
- J9309: 1 billable unit = 1 mg
- Pertinent ICD-10-CM Diagnosis Codes:
  - C83.30 Diffuse large B-cell lymphoma, unspecified site
  - C83.31 Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
  - C83.32 Diffuse large B-cell lymphoma, intrathoracic lymph nodes
  - C83.33 Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
  - C83.34 Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
  - C83.35 Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
  - C83.36 Diffuse large B-cell lymphoma, intrapelvic lymph nodes
  - C83.37 Diffuse large B-cell lymphoma, spleen
  - C83.38 Diffuse large B-cell lymphoma, lymph nodes of multiple sites
  - C83.39 Diffuse large B-cell lymphoma, extranodal and solid organ sites

## VIII. Summary of Policy Changes

- 10/15/19: new policy
- 1/1/20: updated billing/coding

## IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.

*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.*