Medical Coverage Policy | Polivy™ (polatuzumab vedotin-piiq)

EFFECTIVE DATE: 12|01|2019
POLICY LAST UPDATED: 08|06|2019

OVERVIEW

Polivy™ (polatuzumab vedotin-piiq) is indicated, in combination with bendamustine and a rituximab product, for the treatment of adult patients with relapsed refractory diffuse large B-cell lymphoma, not otherwise specified, after at least two prior therapies

This policy is applicable to BlueCHiP for Medicare products only. For Commercial Products, see related policy section.

MEDICAL CRITERIA

Initial Evaluation

Polivy™ (polatuzumab vedotin-piiq) will be approved when ONE of the following are met:

1. There is documentation provided with the request (e.g. treatment start date, length of treatment, patient's clinical benefit from therapy) indicating that the patient is currently being treated with the requested agent

OR

2. ALL of the following:
    a. ONE of the following:
        i. The patient has an FDA labeled indication for the requested agent AND ALL of the following:
            1. ONE of the following:
                a. The requested indication does NOT require genetic/specific diagnostic testing (e.g., ALK, EGFR, HER2, KRAS) in FDA labeling

                OR

                b. The requested indication requires genetic/specific diagnostic testing in the FDA labeling AND ONE of the following:
                    i. BOTH of the following:
                        1. Genetic/diagnostic testing has been performed

                        AND

                        2. The results of the genetic/diagnostic testing indicate therapy with the requested agent is appropriate

                    OR

                    ii. The requested indication does not require genetic/specific diagnostic testing in NCCN with level of evidence 1 or 2a

            AND

            2. ONE of the following:
                a. The requested agent is FDA labeled as a first-line agent for the requested indication

                OR

                b. The patient has used the appropriate number and type(s) of prerequisite agent(s) listed in the FDA labeling for the requested indication

OR

c. The patient has used the appropriate number and type(s) of prerequisite agent(s) supported by NCCN 1 or 2A recommended use for the requested indication

OR

d. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL of the required prerequisite agent(s) listed in the FDA labeling for the requested indication

AND

3. ONE of the following:
   a. The requested agent is approved for use as monotherapy in the FDA labeling for the requested indication

   OR

   b. The requested agent will be used with all agent(s) and/or treatments (e.g., radiation) listed for concomitant use in the FDA labeling for the requested indication

   OR

   c. The requested agent will be used with all agent(s) and/or treatments supported in NCCN 1 or 2a recommended use for the requested indication

AND

4. ONE of the following:
   a. The FDA label does NOT include a performance status requirement

   OR

   b. The patient meets the performance status requirement in the FDA labeling

AND

5. If the client has preferred agents* (*preferred agents determined by client) ONE of the following:
   a. The requested agent is a preferred agent

   OR

   b. The requested agent is a non-preferred agent (Herceptin Hylecta, Infugem) AND ONE of the following:
      i. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL preferred agent(s) for the requested indication and would not be expected to occur with the requested agent

      OR

      ii. The prescriber has submitted documentation in support of the non-preferred agent over the preferred agent(s) for the requested indication (convenience is not a qualified reason)

OR

ii. BOTH of the following:
   1. The use of the target agent is for an indication that is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the use is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic use (approval by the Clinical Review Pharmacist required).

AND

2. If the client has preferred agents* (*preferred agents determined by client) ONE of the following:
    a. The requested agent is a preferred agent

    OR

    b. The requested agent is a non-preferred agent (Herceptin Hylecta, Infugem) AND ONE of the following:
        i. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL preferred agent(s) for the requested indication and would not be expected to occur with the requested agent

        OR

        ii. The prescriber has submitted documentation in support of the non-preferred agent over the preferred agent(s) for the requested indication (convenience is not a qualified reason)

AND

b. The patient does NOT have any FDA labeled contraindications to the requested agent

AND

c. The requested dose is within FDA labeling or dose and duration is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the dose is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic dose (approval by the Clinical Review Pharmacist required)

Length of Approval: 12 months or for duration of treatment as supported in FDA labeling or NCCN compendia, whichever is shorter.

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare.

POLICY STATEMENT

BlueCHiP for Medicare

Polivy™ (polatuzumab vedotin-piiq) is medically necessary when the criteria above have been met.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable physician administered drug benefits/coverage.

BACKGROUND

Clinical Rationale

For the purposes of the Injectable Oncology Agents criteria, indications deemed appropriate are those approved in FDA labeling and/or supported by NCCN Drugs & Biologics compendia with a category 1 or 2A recommendation.

CODING

BlueCHiP for Medicare

There is no specific HCPCS code. Claims must be filed with an unlisted code such as J3490 and the NDC number.

RELATED POLICIES

Prior Authorization of Drugs

PUBLISHED

Provider Update, October 2019

REFERENCES

1. Polivy Prescribing Information. Genentech Inc. June 2019.