Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 160.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Besponsa (inotuzumab ozogamicin)

I. Policy:
Besponsa (inotuzumab ozogamicin)

II. Purpose/Objective:
To provide a policy of coverage regarding Besponsa (inotuzumab ozogamicin)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age

DESCRIPTION:
Besponsa (inotuzumab ozogamicin) is a humanized CD22-directed monoclonal antibody-drug conjugate which is composed of the IgG4 kappa antibody inotuzumab (which is specific for human CD22), a calicheamicin component (a cytotoxic agent that causes double-stranded DNA breaks), and an acid-cleavable linker that covalently binds the calicheamicin to inotuzumab. After the antibody-drug conjugate binds to CD22, the CD22-conjugate complex is internalized, and releases calicheamicin. Calicheamicin binds to the minor groove of DNA to induce double strand cleavage and subsequent cell cycle arrest and apoptosis.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Besponsa (inotuzumab ozogamicin) will be considered medically necessary when ALL of the following criteria are met:

Acute Lymphoblastic Leukemia (ALL)
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥18 years of age **AND**
- Medical record documentation of a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

AUTHORIZATION DURATION: An initial authorization duration of 3 cycles (3 months) should be approved.

Reauthorization: One subsequent authorization will be for an additional 3 cycles (3 months) and will require medical record documentation of the following:
- Medical record documentation that patient is not receiving hematopoietic stem cell transplant (HSCT) **AND**
- Medical record documentation that patient has achieved complete remission or complete remission with incomplete hematologic recovery and minimal residual disease (MRD) **AND**
- Medical record documentation that the patient is not experiencing toxicity or worsening of disease.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 11/21/17

Revised: 6/23/22 (Medicaid PARP statement)

Reviewed: 9/28/18, 8/29/19, 8/26/20, 7/26/21