Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Besponsa (inotuzumab ozogamicin)

DRUG.00110

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Besponsa (inotuzumab ozogamicin)

APPROVAL CRITERIA

Besponsa (inotuzumab ozogamicin) may be approved for the treatment of acute lymphocytic leukemia (ALL) when all of the following criteria are met:

A. Individual is 18 years of age and older; **AND**
B. Individual has relapsed or has refractory disease; **AND**
C. Individual has CD22+ B-cell ALL; **AND**
D. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2.

Besponsa (inotuzumab ozogamicin) **may not be approved** when the criteria above are not met, and for all other indications, including, but not limited to:

A. Use as first-line of therapy for ALL.
B. Use in combination with other chemotherapy agents.

NOTE:

Besponsa (inotuzumab ozogamicin) has black box warnings which include the following information and recommendations:

- Hepatotoxicity, including hepatic veno-occlusive disease (VOD) (Also known as sinusoidal obstruction syndrome and increased risk of post-hematopoietic stem cell transplant (HSCT) non relapse mortality: Hepatotoxicity, including fatal and life-threatening hepatic veno-occlusive disease (VOD) occurred in individuals with relapsed or refractory acute lymphoblastic leukemia (ALL) who received Besponsa. The risk of VOD was greater in individuals who underwent HSCT after Besponsa treatment; use of HSCT conditioning regimens containing 2 alkylating agents and last total bilirubin level ≥ upper limit of normal (ULN) before HSCT were significantly associated with an increased risk of VOD.

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

- Other risk factors for VOD in individuals treated with Besponsa included ongoing or prior liver disease, prior HSCT, increased age, later salvage lines, and a greater number of Besponsa treatment cycles.
- Elevation of liver tests may require dosing interruption, dose reduction, or permanent discontinuation of Besponsa. Permanently discontinue treatment if VOD occurs. If severe VOD occurs, treat according to standard medical practice.
- Increased risk of post-HSCT non-relapse mortality: There was higher post-HSCT non-relapse mortality rate in individuals receiving Besponsa, resulting in a higher Day 100 post-HSCT mortality rate.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

1. Besponsa [Product Information Label]. Philadelphia, PA. Pfizer Inc. August 2017. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761040s000lbl.pdf. Accessed on March 30, 2018.
2. National Comprehensive Cancer Network® NCCN Clinical Practice Guidelines in Oncology™. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on March 30, 2018.
    - Acute Lymphoblastic Leukemia (V1.2018). Revised March 12, 2018.