

BILLING AND CODING INFORMATION FOR HOSPITAL OUTPATIENT

BESPONSA® (inotuzumab ozogamicin) is indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

The table below provides a brief overview of relevant billing and coding information for BESPONSA, presented in greater detail with the sample UB-04/CMS-1450 form on the next page.

Item	Revenue code	Additional coding (HCPCS, ICD-10-CM, and CPT®)	Considerations
Drug: BESPONSA (inotuzumab ozogamicin)¹⁻³ (HCPCS)	Include the appropriate revenue code for each line item based on hospital billing policy, e.g.: Medicare: <ul style="list-style-type: none"> • 0636 - Drugs requiring detailed coding Other payers: <ul style="list-style-type: none"> • 0250 - General Pharmacy OR • 0260 - General Classification (IV Therapy) OR • 0280 - General Classification (Oncology) OR • 0636 - Drugs requiring detailed coding (if required by payer) 	Medicaid, Medicare, and commercial payers: <ul style="list-style-type: none"> • J9229 - Injection, inotuzumab ozogamicin, 0.1 mg Note: Medicare requires the use of the JW modifier (Drug amount discarded/not administered to any patient) when applicable. Other payers' requirements for documenting discarded drug amount, including use of the JW modifier, may vary. Most 340B hospitals must report J9229 with the TB modifier (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes) on Medicare claims when BESPONSA is purchased through the 340B program. For more information on 340B modifiers, go to: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Billing-340B-Modifiers-under-Hospital-OPPS.pdf .	BESPONSA for injection is a white to off-white lyophilized powder supplied in a carton containing one 0.9-mg single-dose vial. Note: 1 unit of J9229 is 0.1mg. 1 vial equals 9 units of J9229.
Diagnosis⁴ (ICD-10-CM)	N/A	<ul style="list-style-type: none"> • C91.00 - Acute lymphoblastic leukemia not having achieved remission OR • C91.01 - Acute lymphoblastic leukemia, in remission OR • C91.02 - Acute lymphoblastic leukemia, in relapse 	Include appropriate ICD-10-CM diagnosis code(s) for patient condition.
Administration^{3,5} (CPT®)	Include appropriate revenue code for the cost center in which the service is performed.	<ul style="list-style-type: none"> • 96413 - Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug OR • 96415 - Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure) 	Include appropriate CPT® code(s) for product administration service(s). BESPONSA is administered by 1-hour IV infusion on Days 1, 8, and 15 of each 3- to 4-week cycle. BESPONSA is supplied as a 0.9 mg single-dose vial. Each vial is reconstituted with 4 mL of Sterile Water for Injection, USP, to obtain a concentration of 0.25 mg/mL of BESPONSA. Please refer to the full Prescribing Information for complete Dosage and Administration instructions.

CPT® is a registered trademark of the American Medical Association.

Call Pfizer Oncology Together for billing and coding questions at 1-877-744-5675 or visit www.PfizerOncologyTogether.com

The information provided in this document is intended for informational purposes only, and is not a comprehensive description of potential coding requirements for BESPONSA. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and accurate and appropriate coding for treatment of his/her own patients. The information provided in this section should not be considered a guarantee of coverage or reimbursement for BESPONSA.

SELECTED IMPORTANT SAFETY INFORMATION

WARNING: 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 (NRM):

- Hepatotoxicity, including fatal and life-threatening VOD, occurred in patients who received BESPONSA. The risk of VOD was greater in patients who underwent HSCT after BESPONSA treatment. The use of HSCT conditioning regimens containing 2 alkylating agents and last total bilirubin \geq upper limit of normal (ULN) before HSCT were significantly associated with an increased risk of VOD
- Other risk factors for VOD in patients 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
- There was a higher post-HSCT non-relapse mortality rate in patients receiving BESPONSA, resulting in a higher Day 100 post-HSCT mortality rate

Please see Important Safety Information on page 3. Please [click here](#) to see full Prescribing Information, including BOXED WARNING, for BESPONSA.



UB-04/CMS-1450 FOR HOSPITAL OUTPATIENT⁶

Revenue Code (Box 42)¹

Enter the appropriate revenue code for each line item based on hospital billing policy, e.g.:

Medicare:

- 0636 - Drugs requiring detailed coding

Other payers:

- 0250 - General Pharmacy
- OR
- 0260 - General Classification (IV Therapy)
- OR
- 0280 - General Classification (Oncology)
- OR
- 0636 - Drugs requiring detailed coding (if required by payer)

Service Units (Box 46)

Note: 1 unit of J9229 is 0.1mg. 1 vial equals 9 units of J9229.

Product Code (Box 44)²

J9229 - Injection, inotuzumab ozogamicin, 0.1 mg

Note: Medicare requires the use of the JW modifier (Drug amount discarded/not administered to any patient) when applicable. Other payers' requirements for documenting discarded drug amount, including use of the JW modifier, may vary.

Most 340B hospitals must report J9229 with the TB modifier (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes) on Medicare claims when BESPONSA is purchased through the 340B program. For more information on 340B modifiers, go to: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Billing-340B-Modifiers-under-Hospital-OPPS.pdf>.

Procedure Code (Box 74)⁵

Enter the appropriate CPT® code(s) for product administration service(s), e.g.:

- 96413 - Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
- OR
- 96415 - Chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to primary procedure)

Diagnosis Code (Box 66DX)⁴

Enter the appropriate ICD-10-CM code, e.g.:

- C91.00 - Acute lymphoblastic leukemia not having achieved remission
- OR
- C91.01 - Acute lymphoblastic leukemia, in remission
- OR
- C91.02 - Acute lymphoblastic leukemia, in relapse

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INDICATION

BESPONSA is indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

IMPORTANT SAFETY INFORMATION

WARNING: 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 (NRM):

- Hepatotoxicity, including fatal and life-threatening VOD, occurred in patients who received BESPONSA. The risk of VOD was greater in patients who underwent HSCT after BESPONSA treatment. The use of HSCT conditioning regimens containing 2 alkylating agents and last total bilirubin \geq upper limit of normal (ULN) before HSCT were significantly associated with an increased risk of VOD
- Other risk factors for VOD in patients 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
- There was a higher post-HSCT non-relapse mortality rate in patients receiving BESPONSA, resulting in a higher Day 100 post-HSCT mortality rate

Hepatotoxicity, Including Hepatic VOD: Hepatotoxicity, including fatal and life-threatening VOD, occurred in 23/164 patients (14 %) during or following treatment with BESPONSA or following subsequent HSCT. VOD was reported up to 56 days after the last dose during treatment or follow-up without an intervening HSCT. The median time from HSCT to onset of VOD was 15 days.

Patients with prior VOD or serious ongoing liver disease are at an increased risk of worsening liver disease, including development of VOD, following treatment with BESPONSA. Monitor closely for signs and symptoms of VOD; these may include elevations in total bilirubin, hepatomegaly (which may be painful), rapid weight gain, and ascites. For patients proceeding to HSCT, the recommended duration of treatment with BESPONSA is 2 cycles. A third cycle may be considered for patients who do not achieve a CR or CRi and MRD-negativity after 2 cycles. Monitor liver tests closely during the first month post HSCT, then less frequently thereafter, according to standard medical practice.

Grade 3/4 increases in aspartate aminotransferase, alanine aminotransferase, and total bilirubin occurred in 7/160 (4 %), 7/161 (4 %), and 8/161 (5 %) patients, respectively.

Increased Risk of Post-HSCT Non-Relapse Mortality (NRM): There was a higher post-HSCT NRM rate in patients receiving BESPONSA, resulting in a higher Day 100 post-HSCT mortality rate. The rate of post-HSCT NRM was 31/79 (39 %) with BESPONSA and 8/35 (23 %) with investigator's choice of chemotherapy. In the BESPONSA arm, the most common causes of post-HSCT NRM included VOD and infections. Monitor closely for toxicities post HSCT, including signs and symptoms of infection and VOD.

Myelosuppression: Myelosuppression, and severe, life-threatening, and fatal complications of myelosuppression, including hemorrhagic events and infections, have occurred with BESPONSA. Thrombocytopenia and neutropenia were reported in 83/164 patients (51 %) and 81/164 patients (49 %), respectively. Febrile neutropenia was reported in 43/164 patients (26 %).

Monitor complete blood counts prior to each dose of BESPONSA and monitor for signs and symptoms of infection, bleeding/hemorrhage, or other effects of myelosuppression during treatment and provide appropriate management. As appropriate, administer prophylactic anti-infectives during and after treatment with BESPONSA. Dose interruption, dose reduction, or permanent discontinuation may be required.

Infusion-Related Reactions: Infusion-related reactions (all Grade 2) were reported in 4/164 patients (2 %). Premedicate with a corticosteroid, antipyretic, and antihistamine prior to dosing. Monitor patients closely during and for at least 1 hour after the end of the infusion for the potential onset of infusion-related reactions including symptoms such as fever, chills, rash, or breathing problems. Interrupt the infusion and institute appropriate medical management if an infusion-related reaction occurs. Depending on the severity, consider discontinuation of the infusion or administration of steroids and antihistamines. For severe or life-threatening infusion reactions, permanently discontinue BESPONSA.

QT Interval Prolongation: Increases in QT interval corrected for heart rate using Fridericia's formula of ≥ 60 msec from baseline were measured in 4/162 patients (3 %). Administer BESPONSA with caution in patients who have a history of or predisposition to QTc prolongation, who are taking medicinal products that are known to prolong QT interval, and in patients with electrolyte disturbances. Obtain electrocardiograms and electrolytes prior to treatment and after initiation of any drug known to prolong QTc, and periodically monitor as clinically indicated during treatment.

Embryo-Fetal Toxicity: BESPONSA can cause embryo-fetal harm. Apprise pregnant women of the potential risk to the fetus. Advise males and females of reproductive potential to use effective contraception during BESPONSA treatment and for at least 5 and 8 months after the last dose, respectively. Advise women to contact their healthcare provider if they become pregnant or if pregnancy is suspected during treatment with BESPONSA.

Adverse Reactions: The most common (≥ 20 %) adverse reactions observed with BESPONSA were thrombocytopenia, neutropenia, infection, anemia, leukopenia, fatigue, hemorrhage, pyrexia, nausea, headache, febrile neutropenia, transaminases increased, abdominal pain, gamma-glutamyltransferase increased, and hyperbilirubinemia. The most common (≥ 2 %) serious adverse reactions were infection, febrile neutropenia, hemorrhage, abdominal pain, pyrexia, VOD, and fatigue.

Nursing Mothers: Advise women against breastfeeding while receiving BESPONSA and for 2 months after the last dose.

Please [click here](#) to see the full Prescribing Information, including BOXED WARNING, for BESPONSA.

References: 1. Centers for Medicare & Medicaid Services website. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r167cp.pdf>. CMS Manual System Pub 100-04/Transmittal 167. Published April 30, 2004. Accessed May 2, 2017. 2. Centers for Medicare & Medicaid Services website. <https://www.cms.gov/Medicare/Coding/HCPSCReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2016-Alpha-Numeric-HCPCS-File.html>. Accessed May 2, 2017. 3. BESPONSA Prescribing Information. New York, NY: Pfizer Inc. 4. Centers for Medicare & Medicaid Services website. ICD-10-CM Tabular List of Diseases and Injuries. <https://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-CM-and-GEMS.html>. Accessed May 2, 2017. 5. Hollmann PA, et al, eds. *Current Procedural Terminology*. 4th rev ed. Chicago, IL: American Medical Association; 2015. 6. Centers for Medicare & Medicaid Services website. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r1104cp.pdf>. CMS Manual System Pub 100-04/Transmittal 1104. Published November 3, 2006. Accessed May 2, 2017.