AUCATZYL®

obecabtagene autoleucel

suspension for IV infusion

Coding and Billing Guide

US-AUC-0018 11/24 V1

Please see **Important Safety Information** on pages 22-24 and full **Prescribing Information, including BOXED WARNING**.

Introduction and contents

AUCATZYL®
obecabtagene autoleucel
suspension for IV infusion

This guide contains important information and relevant considerations to help Authorized Treatment Centers navigate AUCATZYL payer access for appropriate patients. The process involves multiple steps to ensure quality of care. Patient status is at the sole discretion of the healthcare provider. This guide is intended to provide general information for AUCATZYL coding and billing. However, specific requirements may vary depending on payer and individual patient circumstances.

Included content topics:

AUCATZYL OVERVIEW

- Treatment process
- Dosing and administration

COVERAGE AND REIMBURSEMENT

- Coverage considerations
- Benefits Verification Checklist
- Prior Authorization Checklist
- Template letters
- Reimbursement considerations

CODING AND BILLING

- Coding summary
- Relevant codes
- Billing implications
- Sample claim forms

AUTOLUSASSIST™ SUPPORT

- Patient support services

Coding, billing, coverage, and reimbursement information in this guide is based on various published sources as of November 2024. It is general in nature and subject to change. The guide is not meant to capture various payer-specific requirements. It does not provide guarantee of coverage or reimbursement. The healthcare provider is responsible for confirming eligibility, coverage conditions, reimbursement methodology, and coding and billing requirements with each prospective patient's payer. Selecting appropriate codes and ensuring claim accuracy based on medical record documentation is the sole responsibility of the healthcare provider.

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AUCATZYL treatment journey

AUCATZYL® obecabtagene autoleucel
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AUCATZYL has a unique treatment process that encompasses multiple milestones, including bone marrow assessment to determine the dosing regimen and 2 AUCATZYL infusions.[1]

Patient Identification	Leukapheresis	Manufacturing*	Bone Marrow Assessment	Lymphodepletion	1st AUCATZYL Infusion	Monitoring and Follow-up	2nd AUCATZYL Infusion	Monitoring and Follow-up
								
Patient eligibility for AUCATZYL confirmed	Patient's peripheral blood mononuclear cells collected	Patient's T cells modified and CAR-positive T cells expanded†	Bone marrow blast percentage determined (ie, tumor burden) to guide the AUCATZYL dosing regimen	Lymphodepleting chemotherapy regimen administered	AUCATZYL dosing regimen initiated (ie, 1st split dose infused)	Monitoring for signs and symptoms of CRS, ICANS, and other toxicities	AUCATZYL dosing regimen completed (ie, 2nd split dose infused)	Continued monitoring for signs and symptoms of CRS, ICANS, and other toxicities

TREATMENT SCHEDULE

Between days -13 and -7	Days -6 to -3	Day 1‡	Starting on Day 1	Day 10 (±2 days)§	For ≥4 weeks after each infusion
(within 7 days prior to the start of lymphodepletion)	*(for 4 days)*		*(following the 1st infusion)*		

Daily for ≥14 days after the 1st infusion

AUCATZYL is available only at Authorized Treatment Centers (ATCs), which have been certified by Autolus to treat patients with AUCATZYL

*In the pivotal FELIX trial, the median time from leukapheresis to product release was 20 days (range: 17 to 23 days).[1]
†During the manufacturing process, patients may receive bridging therapy for disease control.[1]
‡First AUCATZYL infusion is administered 3 days (±1 days) after completion of lymphodepleting chemotherapy treatment (Day 1), allowing a minimum 48-hour washout.[1]
§Second AUCATZYL infusion is administered on Day 10 (±2 days) after the first infusion; however, a delay to the second split dose (up to Day 21) or treatment discontinuation may be required to manage toxicities.[1]
CAR=chimeric antigen receptor; CRS=cytokine release syndrome; ICANS=immune effector cell-associated neurotoxicity syndrome.

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AUCATZYL dosing and administration

AUCATZYL® obecabtagene autoleucel
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The total recommended dose of AUCATZYL is 410×10^6 CAR-positive viable T cells NDC (83047-410-04) supplied in 3 to 5 infusion bags. AUCATZYL is administered intravenously per tumor burden–guided dosing regimen, which includes 2 separate split-dose infusions.[1]

TUMOR BURDEN*	1st AUCATZYL INFUSION ON DAY 1†	2nd AUCATZYL INFUSION ON DAY 10‡	TOTAL RECOMMENDED DOSE
Bone Marrow Blast ≤20%	100×10^6 CAR T Cells	310×10^6 CAR T Cells	**410×10^6 CAR T Cells**
Bone Marrow Blast >20%	10×10^6 CAR T Cells	400×10^6 CAR T Cells	

AUCATZYL is supplied in 3 to 5 infusion bags containing the total recommended dose for administration in 2 separate infusions[1]

*Bone marrow assessment is performed within 7 days prior to the start of lymphodepletion to determine dosing regimen.[1]
†First AUCATZYL infusion is administered 3 days (±1 days) after completion of lymphodepleting chemotherapy treatment (Day 1), allowing a minimum 48-hour washout.[1]
‡Second AUCATZYL infusion is administered on Day 10 (±2 days) after the first infusion; however, a delay to the second split dose (up to Day 21) or treatment discontinuation may be required to manage toxicities.[1]
CAR=chimeric antigen receptor; NDC=National Drug Code.

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Payer coverage and prior authorization considerations for AUCATZYL

AUCATZYL® obecabtagene autoleucel suspension for IV infusion

For AUCATZYL coverage and prior authorization (PA), payers are expected to use similar approaches as with other FDA-approved CAR T-cell therapies. However, requirements may vary by payer. Therefore, it is important for ATCs to confirm specific requirements and to verify patient benefits.

COMMERCIAL	MEDICARE FFS	MEDICARE ADVANTAGE	MEDICAID
Plan-specific medical policy requirements may vary*	Coverage per NCD 110.24[2]	Coverage per NCD 110.24; plan-specific medical policy requirements may vary[2,3]*	State and/or plan-specific requirements may vary*
PA likely to be required per payer policy*	PA not utilized for CAR T	PA likely to be required per payer policy*	PA likely to be required per payer policy*

Proactive engagement with the ATC's top payers is critical for avoiding potential access delays

*Commercial and Medicare Advantage coverage policies are generally expected to be published within several months of the FDA approval of AUCATZYL. Publication of Medicaid coverage policies may take longer; some state Medicaid programs may not publish any CAR T coverage policies. If a payer has not published an AUCATZYL coverage policy, they may review coverage/PA requests on a case-by-case basis.

ATC=Authorized Treatment Center; CAR=chimeric antigen receptor; FDA=US Food and Drug Administration; FFS=fee-for-service; NCD=national coverage determination.

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Benefits Verification Checklist for AUCATZYL

AUCATZYL® obecabtagene autoleucel suspension for IV infusion

BV is a key component of the revenue integrity process for healthcare providers. During the BV process, ATCs can investigate patient benefits and confirm payer-specific requirements for AUCATZYL.

BENEFITS AND PATIENT RESPONSIBILITY

- ☐ Health insurance eligibility and plan priority (eg, primary, secondary, supplemental, catastrophic plan)
- ☐ Coordination of benefits by plan eligibility
- ☐ Cost-sharing responsibility for inpatient and outpatient services
- ☐ Amount paid in the benefit year toward the deductible and/or out-of-pocket maximum (if applicable)
- ☐ Applicable center of excellence requirements and related cost-sharing implications

COVERAGE CONDITIONS

- ☐ Covered benefits across the AUCATZYL treatment journey
- ☐ PA requirements for each step in the treatment process
- ☐ AUCATZYL coverage policy criteria
- ☐ Peer-to-peer review process if needed
- ☐ Out-of-network and/or out-of-state restrictions
- ☐ Payer-specific billing considerations

For BV support, contact your ATC's dedicated AutolusAssist™ Case Manager at 1-855-288-5227

ATC=Authorized Treatment Center; BV=benefits verification; PA=prior authorization.

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Prior Authorization Checklist for AUCATZYL

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Commercial, Medicare Advantage, and Medicaid payers may require PA for CAR T-cell therapy, including AUCATZYL. The PA process may require submission of a payer- and plan-specific PA request form, clinical records and documentation to support AUCATZYL medical necessity, and other additional information. Although PA requirements for CAR T-cell therapies are often based on FDA-approved labeling and patient eligibility criteria in clinical trials, specific PA requirements for AUCATZYL may vary by payer and patient benefits.

INVESTIGATING AUCATZYL PA REQUIREMENTS FOR PATIENT'S PAYER

- ☐ Locate relevant payer coverage policy and/or PA form for AUCATZYL

  Note: If AUCATZYL policy or PA form has not been published, follow the payer's general process for medical necessity requests
- ☐ Review PA process requirements for the entirety of the AUCATZYL treatment journey. This includes tumor burden–guided dosing (split-dose infusions)
- ☐ Determine if the patient may qualify for expedited PA or medical necessity review

COLLECTING CLINICAL INFORMATION FOR AUCATZYL PA

Potential examples of PA documentation requirements:

- ☐ R/R adult B-ALL diagnosis
- ☐ Bone marrow assessment
- ☐ CD19 positivity
- ☐ Response to and timing of prior treatment
- ☐ ECOG performance status score
- ☐ Adequate kidney, liver, lung, and/or heart function

SUBMITTING AUCATZYL PA REQUEST

- ☐ Ensure complete and accurate information

  Note: It may be helpful to include a summary of submitted information for specific PA criteria
- ☐ Consider attaching the following supplemental information as needed:
  - FDA approval letter (visit the FDA website)
  - Prescribing Information
  - ATC designation by Autolus
  - Letter of Medical Necessity
- ☐ Consider requesting peer-to-peer review if needed

APPEALING AUCATZYL PA DENIALS (if needed)

- ☐ Review payer's denial letter
- ☐ Submit a letter of appeal with a clear rationale for coverage reconsideration and medical necessity

  Note: It is important to address specific reason(s) stated in the payer's denial letter
- ☐ Consider requesting peer-to-peer review

For PA support, contact your ATC's dedicated AutolusAssist™ Case Manager at 1-855-288-5227

ATC=Authorized Treatment Center; CAR=chimeric antigen receptor; ECOG=Eastern Cooperative Oncology Group; FDA=US Food and Drug Administration; PA=prior authorization; R/R=relapsed/refractory.

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Template letters for AUCATZYL

AUCATZYL®
obecabtagene autoleucel
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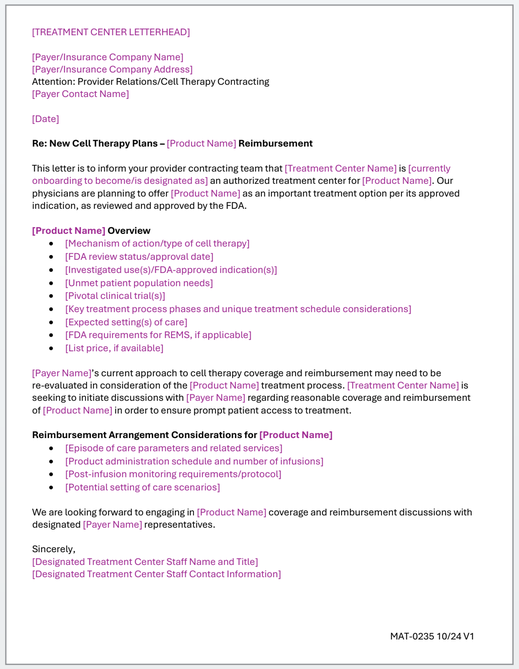
The following template letters are available at AutolusAssist.com to help support treatment center communications with payers regarding AUCATZYL coverage and reimbursement.



[TREATMENT CENTER LETTERHEAD]

[Payer/Insurance Company Name]
[Payer/Insurance Company Address]
Attention: Provider Relations/Cell Therapy Contracting
[Payer Contact Name]

[Date]

Re: New Cell Therapy Plans – [Product Name] Reimbursement

This letter is to inform your provider contracting team that [Treatment Center Name] is [currently onboarding to become/is designated as] an authorized treatment center for [Product Name]. Our physicians are planning to offer [Product Name] as an important treatment option per its approved indication, as reviewed and approved by the FDA.

[Product Name] Overview

- [Mechanism of action/type of cell therapy]
- [FDA review status/approval date]
- [Investigated use(s)/FDA-approved indication(s)]
- [Unmet patient population needs]
- [Pivotal clinical trial(s)]
- [Key treatment process phases and unique treatment schedule considerations]
- [Expected setting(s) of care]
- [FDA requirements for REMS, if applicable]
- [List price, if available]

[Payer Name]'s current approach to cell therapy coverage and reimbursement may need to be re-evaluated in consideration of the [Product Name] treatment process. [Treatment Center Name] is seeking to initiate discussions with [Payer Name] regarding reasonable coverage and reimbursement of [Product Name] in order to ensure prompt patient access to treatment.

Reimbursement Arrangement Considerations for [Product Name]

- [Episode of care parameters and related services]
- [Product administration schedule and number of infusions]
- [Post-infusion monitoring requirements/protocol]
- [Potential setting of care scenarios]

We are looking forward to engaging in [Product Name] coverage and reimbursement discussions with designated [Payer Name] representatives.

Sincerely,
[Designated Treatment Center Staff Name and Title]
[Designated Treatment Center Staff Contact Information]

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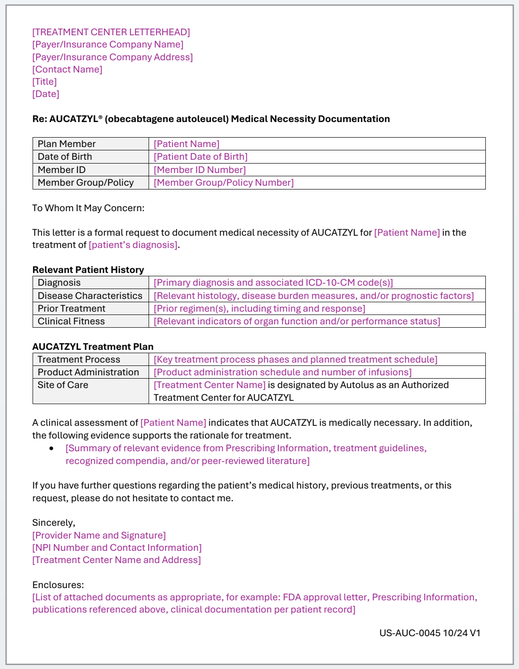
Letter of Intent Template

Click here



[TREATMENT CENTER LETTERHEAD]
[Payer/Insurance Company Name]
[Payer/Insurance Company Address]
[Contact Name]
[Title]
[Date]

Re: AUCATZYL® (obecabtagene autoleucel) Medical Necessity Documentation

Plan Member	[Patient Name]
Date of Birth	[Patient Date of Birth]
Member ID	[Member ID Number]
Member Group/Policy	[Member Group/Policy Number]

To Whom It May Concern:

This letter is a formal request to document medical necessity of AUCATZYL for [Patient Name] in the treatment of [patient's diagnosis].

Relevant Patient History

Diagnosis	[Primary diagnosis and associated ICD-10-CM code(s)]
Disease Characteristics	[Relevant histology, disease burden measures, and/or prognostic factors]
Prior Treatment	[Prior regimen(s), including timing and response]
Clinical Fitness	[Relevant indicators of organ function and/or performance status]

AUCATZYL Treatment Plan

Treatment Process	[Key treatment process phases and planned treatment schedule]
Product Administration	[Product administration schedule and number of infusions]
Site of Care	[Treatment Center Name] is designated by Autolus as an Authorized Treatment Center for AUCATZYL

A clinical assessment of [Patient Name] indicates that AUCATZYL is medically necessary. In addition, the following evidence supports the rationale for treatment.

- [Summary of relevant evidence from Prescribing Information, treatment guidelines, recognized compendia, and/or peer-reviewed literature]

If you have further questions regarding the patient's medical history, previous treatments, or this request, please do not hesitate to contact me.

Sincerely,
[Provider Name and Signature]
[NPI Number and Contact Information]
[Treatment Center Name and Address]

Enclosures:
[List of attached documents as appropriate, for example: FDA approval letter, Prescribing Information, publications referenced above, clinical documentation per patient record]

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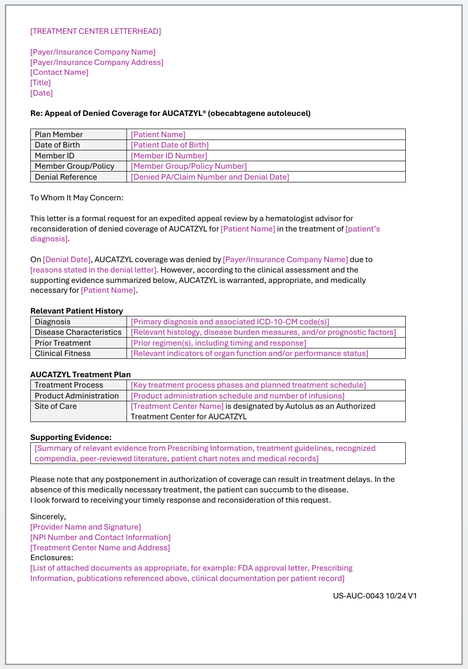
Letter of Medical Necessity Template

Click here



[TREATMENT CENTER LETTERHEAD]

[Payer/Insurance Company Name]
[Payer/Insurance Company Address]
[Contact Name]
[Title]
[Date]

Re: Appeal of Denied Coverage for AUCATZYL® (obecabtagene autoleucel)

Plan Member	[Patient Name]
Date of Birth	[Patient Date of Birth]
Member ID	[Member ID Number]
Member Group/Policy	[Member Group/Policy Number]
Denial Reference	[Denied PA/Claim Number and Denial Date]

To Whom It May Concern:

This letter is a formal request for an expedited appeal review by a hematologist advisor for reconsideration of denied coverage of AUCATZYL for [Patient Name] in the treatment of [patient's diagnosis].

On [Denial Date], AUCATZYL coverage was denied by [Payer/Insurance Company Name] due to [reasons stated in the denial letter]. However, according to the clinical assessment and the supporting evidence summarized below, AUCATZYL is warranted, appropriate, and medically necessary for [Patient Name].

Relevant Patient History

Diagnosis	[Primary diagnosis and associated ICD-10-CM code(s)]
Disease Characteristics	[Relevant histology, disease burden measures, and/or prognostic factors]
Prior Treatment	[Prior regimen(s), including timing and response]
Clinical Fitness	[Relevant indicators of organ function and/or performance status]

AUCATZYL Treatment Plan

Treatment Process	[Key treatment process phases and planned treatment schedule]
Product Administration	[Product administration schedule and number of infusions]
Site of Care	[Treatment Center Name] is designated by Autolus as an Authorized Treatment Center for AUCATZYL

Supporting Evidence:

[Summary of relevant evidence from Prescribing Information, treatment guidelines, recognized compendia, peer-reviewed literature, patient chart notes and medical records]

Please note that any postponement in authorization of coverage can result in treatment delays. In the absence of this medically necessary treatment, the patient can succumb to the disease.
I look forward to receiving your timely response and reconsideration of this request.

Sincerely,
[Provider Name and Signature]
[NPI Number and Contact Information]
[Treatment Center Name and Address]
Enclosures:
[List of attached documents as appropriate, for example: FDA approval letter, Prescribing Information, publications referenced above, clinical documentation per patient record]

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Letter of Appeal Template

Click here

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Payer reimbursement considerations for AUCATZYL

AUCATZYL® obecabtagene autoleucel suspension for IV infusion

For AUCATZYL reimbursement, payers are expected to use similar methodologies as with other FDA-approved CAR T-cell therapies. However, requirements may vary by payer, patient benefits, and/or patient status.

COMMERCIAL	MEDICARE FFS	MEDICARE ADVANTAGE	MEDICAID
Reimbursement methodologies vary by payer and contract terms (case rate may apply)	INPATIENT: MS-DRG 018 payment rate under IPPS* (outlier payment may apply based on reported charges)[4]	Reimbursement methodologies vary by payer and contract terms (DRG-based payment may apply)	Reimbursement methodologies vary by state and/or Medicaid plan
Single case agreement likely to be required	OUTPATIENT: APC payment under OPPS, including separate reimbursement for AUCATZYL and CAR T administration[5,6†]	Single case agreement likely to be required	Single case agreement may be required
Separate reimbursement for AUCATZYL may be possible depending on contract		Separate reimbursement for AUCATZYL may be possible depending on contract	In some states, AUCATZYL may be carved out from typical payment methodologies

Proactive engagement with the ATC's top payers is critical for avoiding potential access delays

*ICD-10-PCS codes for AUCATZYL administration have been mapped to MS-DRG 018.[4] For applicable clinical trial or expanded use access claims, Medicare FFS will adjust payment rate for MS-DRG 018.[4] For more information on clinical trial and expanded access billing, refer to the American Society for Transplantation and Cellular Therapy (ASTCT) CAR T Therapy Coding and Billing Guide.[7]

†CPT code for CAR T administration is assigned to APC 5694.[5,6]

APC=Ambulatory Payment Classification; ATC=Authorized Treatment Center; CAR=chimeric antigen receptor; CPT=Current Procedural Terminology; FDA=US Food and Drug Administration; FFS=fee-for-service; ICD-10-PCS=International Classification of Diseases, Tenth Revision, Procedure Coding System; IPPS=Inpatient Prospective Payment System; MS-DRG=Medicare Severity Diagnosis Related Group; OPPS=Outpatient Prospective Payment System.

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Summary of relevant codes for AUCATZYL

AUCATZYL® obecabtagene autoleucel suspension for IV infusion

CODE TYPE	CODE	DESCRIPTION
ICD-10-CM Diagnosis Codes[8]	C91.00	Acute lymphoblastic leukemia not having achieved remission
	C91.02	Acute lymphoblastic leukemia, in relapse
	Z51.12	Encounter for antineoplastic immunotherapy
HCPCS Level II Product Codes[9]	J3490	Unclassified drugs
	J3590	Unclassified biologics
	C9399	Unclassified drugs or biologicals
NDC Product Code[1]	11-digit format: 83047-0410-04	AUCATZYL 410×10⁶ CD19 CAR-positive viable T cells total recommended dose supplied in 3 to 5 bags
ICD-10-PCS Procedure Codes[10]	XW0338A	Introduction of obecabtagene autoleucel into peripheral vein, percutaneous approach, new technology group 10
	XW0438A	Introduction of obecabtagene autoleucel into central vein, percutaneous approach, new technology group 10

CODE TYPE	CODE	DESCRIPTION
CPT® Procedure Codes[6]	0537T (expires at the end of 2024) 38225 (in effect starting in 2025)	Chimeric antigen receptor T cell (CAR T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR T cells, per day
	0538T (expires at the end of 2024) 38226 (in effect starting in 2025)	Chimeric antigen receptor T cell (CAR T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)
	0539T (expires at the end of 2024) 38227 (in effect starting in 2025)	Chimeric antigen receptor T cell (CAR T) therapy; receipt and preparation of CAR T cells for administration
	0540T (expires at the end of 2024) 38228 (in effect starting in 2025)	Chimeric antigen receptor T cell (CAR T) therapy; CAR T cell administration, autologous
Hospital Revenue Codes[3]	0871	Cell/gene therapy – cell collection
	0872	Cell/gene therapy – specialized biologic processing and storage – prior to transport
	0873	Cell/gene therapy – storage and processing after receipt of cells from manufacturer
	0874	Cell/gene therapy – infusion of modified cells
	0891	Special processed drugs – FDA-approved cell therapy

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CAR=chimeric antigen receptor; CPT=Current Procedural Terminology; FDA=US Food and Drug Administration; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; ICD-10-PCS=International Classification of Diseases, Tenth Revision, Procedure Coding System; NDC=National Drug Code.

Please see **Important Safety Information** on pages 22-24 and full **Prescribing Information, including BOXED WARNING**.

Diagnosis coding: ICD-10-CM

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The following ICD-10-CM diagnosis codes are potentially relevant for patients receiving AUCATZYL treatment. It is important to verify specific payer requirements with respect to diagnosis coding for AUCATZYL. In addition, the reported diagnosis code should reflect the highest level of specificity documented in the patient's medical record.

ICD-10-CM CODE[8]	DESCRIPTION
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.02	Acute lymphoblastic leukemia, in relapse
Z51.12	Encounter for antineoplastic immunotherapy

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ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

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Product coding: HCPCS Level II

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As a newly approved cell therapy, AUCATZYL has not been assigned a unique HCPCS code in 2024. Autolus plans to submit for pass-through payment designation and a permanent HCPCS code for AUCATZYL by the end of 2024. Until a specific AUCATZYL code is in effect, an unspecified/miscellaneous code should be used. It is important to verify specific payer requirements with respect to unspecified/miscellaneous coding, as well as reporting of additional information for AUCATZYL (eg, product name, administered quantity, NDC).

HCPCS LEVEL II CODE[9]	DESCRIPTION	NOTES
J3490	Unclassified drugs	Payer requirements may vary.
J3590	Unclassified biologics	
C9399	Unclassified drugs or biologicals	Required by Medicare FFS for outpatient hospital claims until a specific HCPCS code is assigned for AUCATZYL.[11*†]

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*Medicare FFS requirement for reporting the JZ and JW modifiers does not apply to claims with C9399 billed under the OPPS; it applies to separately payable drugs from single-dose containers assigned OPPS status indicators "G" or "K".[12]

†Starting in January 2025, the TB modifier must be reported on claims billed under the OPPS for drugs acquired through the 340B Drug Pricing Program.[13]

FFS=fee-for-service; HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code; OPPS=Outpatient Prospective Payment System.

Please see **Important Safety Information** on pages 22-24 and full **Prescribing Information, including BOXED WARNING**.

Product coding: NDC

AUCATZYL® obecabtagene autoleucel suspension for IV infusion

AUCATZYL is sent to ATCs as a single shipment containing the total recommended dose for administration in 2 separate infusions.[1] AUCATZYL total recommended dose (410×10^6 CAR-positive viable T cells) is supplied in 3 to 5 infusion bags containing a frozen suspension of genetically modified autologous T cells in PBS, HSA, EDTA, and 7.5% DMSO.[1] Each infusion bag of AUCATZYL is individually packed within an overwrap and then enclosed within a metal cassette.[1]

Five NDC numbers are assigned to AUCATZYL, with 1 NDC for the kit containing the total treatment of AUCATZYL. It is important to verify specific payer requirements with respect to NDC reporting on medical claims.

NDC[1]	DESCRIPTION[1]	NOTES
11-digit format: 83047-0410-04 **10-digit format: 83047-410-04**	AUCATZYL 410×10^6 CD19 CAR-positive viable T cells total recommended dose supplied in 3 to 5 bags, including: • 10×10^6 CD19 CAR-positive viable T cells in 1 50-mL infusion bag • 100×10^6 CD19 CAR-positive viable T cells in 1 or more 50-mL infusion bags or in one 250-mL infusion bag • 300×10^6 CD19 CAR-positive viable T cells in 1 or more 250-mL infusion bags	11-digit format is typically used for medical billing. For Medicaid and Medicare dual-eligible patients, reporting format may require N4 qualifier, NDC quantity qualifier, and the quantity.[14] • Example: N483047041004UN1

AUCATZYL is supplied in a kit represented by 1 NDC containing the total treatment dose to be administered in 2 separate infusions, which may occur in separate encounters

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ATC=Authorized Treatment Center; CAR=chimeric antigen receptor; DMSO=dimethyl sulfoxide; EDTA=ethylenediaminetetraacetic acid; HSA=human serum albumin; NDC=National Drug Code; PBS=phosphate buffered saline.

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Procedure coding: ICD-10-PCS

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Effective October 1, 2024, 2 ICD-10-PCS codes have been implemented by CMS for reporting inpatient administration of AUCATZYL.[4]

ICD-10-PCS CODE[10]	DESCRIPTION	IPPS CONSIDERATIONS FOR MEDICARE PATIENTS
XW0338A	Introduction of obecabtagene autoleucel into peripheral vein, percutaneous approach, new technology group 10	Medicare cases map to MS-DRG 018 (Chimeric Antigen Receptor [CAR] T cell and Other Immunotherapies).[4]
XW0438A	Introduction of obecabtagene autoleucel into central vein, percutaneous approach, new technology group 10	

Coding, billing, coverage, and reimbursement information in this guide is based on various published sources as of November 2024. It is general in nature and subject to change. The guide is not meant to capture various payer-specific requirements. It does not provide guarantee of coverage or reimbursement. The healthcare provider is responsible for confirming eligibility, coverage conditions, reimbursement methodology, and coding and billing requirements with each prospective patient's payer. Selecting appropriate codes and ensuring claim accuracy based on medical record documentation is the sole responsibility of the healthcare provider.

CMS=Centers for Medicare and Medicaid Services; ICD-10-PCS=International Classification of Diseases, Tenth Revision, Procedure Coding System; IPPS=Inpatient Prospective Payment System; MS-DRG=Medicare Severity Diagnosis Related Group.

Please see **Important Safety Information** on pages 22-24 and full **Prescribing Information, including BOXED WARNING**.

Procedure coding: CPT® (HCPCS Level I)

AUCATZYL® obecabtagene autoleucel
suspension for IV infusion

In 2019, 4 CPT Category III codes were established for reporting CAR T services.[3] In 2025, they will be replaced with permanent CPT Category I codes.[6]
It is important to verify specific payer requirements with respect to CPT reporting.

CPT CATEGORY III CODE in effect on or after December 31, 2024[6]	CPT CATEGORY I CODE in effect on or after January 1, 2025[6]	DESCRIPTION	CY 2024/CY 2025 OPPS CONSIDERATIONS FOR MEDICARE FFS PATIENTS[3,5,6]
0537T	38225	Chimeric antigen receptor T cell (CAR T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR T cells, per day	No assigned APC (can be reported for tracking purposes)
0538T	38226	Chimeric antigen receptor T cell (CAR T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)	
0539T	38227	Chimeric antigen receptor T cell (CAR T) therapy; receipt and preparation of CAR T cells for administration	
0540T	38228	Chimeric antigen receptor T cell (CAR T) therapy; CAR T cell administration, autologous	Assigned to APC 5694 *Note: The FDA does not require a REMS for AUCATZYL. Contact your regional A/B MAC to confirm KX modifier reporting requirements**

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*According to the transmittal 11179, outpatient facilities must attest that they are REMS-certified by appending the KX modifier to the CAR T administration code 0540T.[7,15]

A/B MAC=Part A and B Medicare Administrative Contractor; APC=Ambulatory Payment Classification; CAR=chimeric antigen receptor; CPT=Current Procedural Terminology; CY=calendar year; FDA=US Food and Drug Administration; FFS=fee-for-service; HCPCS=Healthcare Common Procedure Coding System; OPPS=Outpatient Prospective Payment System; REMS=Risk Evaluation and Mitigation Strategy.

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Hospital revenue coding

AUCATZYL® obecabtagene autoleucel
suspension for IV infusion

Five hospital revenue codes have been established by the National Uniform Billing Committee for reporting CAR T services and related hospital facility charges.[3,16] Considering that AUCATZYL total recommended dose is administered in 2 split-dose infusions,[1] it is important to verify specific payer billing requirements for reporting the 2 AUCATZYL infusions.

REVENUE CODE[3]	DESCRIPTION	CORRESPONDING HCPCS CODE[3,6]
0871	Cell/gene therapy – cell collection	**0537T in 2024; 38225 in 2025**
0872	Cell/gene therapy – specialized biologic processing and storage – prior to transport	**0538T in 2024; 38226 in 2025**
0873	Cell/gene therapy – storage and processing after receipt of cells from manufacturer	**0539T in 2024; 38227 in 2025**
0874	Cell/gene therapy – infusion of modified cells	**0540T in 2024; 38228 in 2025**
0891*	Special processed drugs – FDA-approved cell therapy	**Appropriate C-code, J-code, or Q-code for AUCATZYL** (eg, C9399 in 2024)

Coding, billing, coverage, and reimbursement information in this guide is based on various published sources as of November 2024. It is general in nature and subject to change. The guide is not meant to capture various payer-specific requirements. It does not provide guarantee of coverage or reimbursement. The healthcare provider is responsible for confirming eligibility, coverage conditions, reimbursement methodology, and coding and billing requirements with each prospective patient's payer. Selecting appropriate codes and ensuring claim accuracy based on medical record documentation is the sole responsibility of the healthcare provider.

*Value code 90 can be used to report cell therapy invoice cost.[7,16]

CAR=chimeric antigen receptor; FDA=US Food and Drug Administration; HCPCS=Healthcare Common Procedure Coding System.

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AUCATZYL billing implications

AUCATZYL® obecabtagene autoleucel
suspension for IV infusion

AUCATZYL is manufactured from a patient's cellular material to supply a total recommended dose (supplied in a kit represented by NDC 83047-410-04) which is given in 2 split-dose infusions.[1]

ATCs will be invoiced once for the supplied AUCATZYL total recommended dose. Administration services for the 2 split-dose infusions may be ordered to occur over multiple encounters and billed on separate claims. ATCs should consult with the payer and plan for billing requirements related to the reporting of the 2 AUCATZYL infusions.

1st AUCATZYL Infusion*

2nd AUCATZYL Infusion†

AUCATZYL is invoiced for the total supplied recommended dose to be given in 2 split-dose infusions

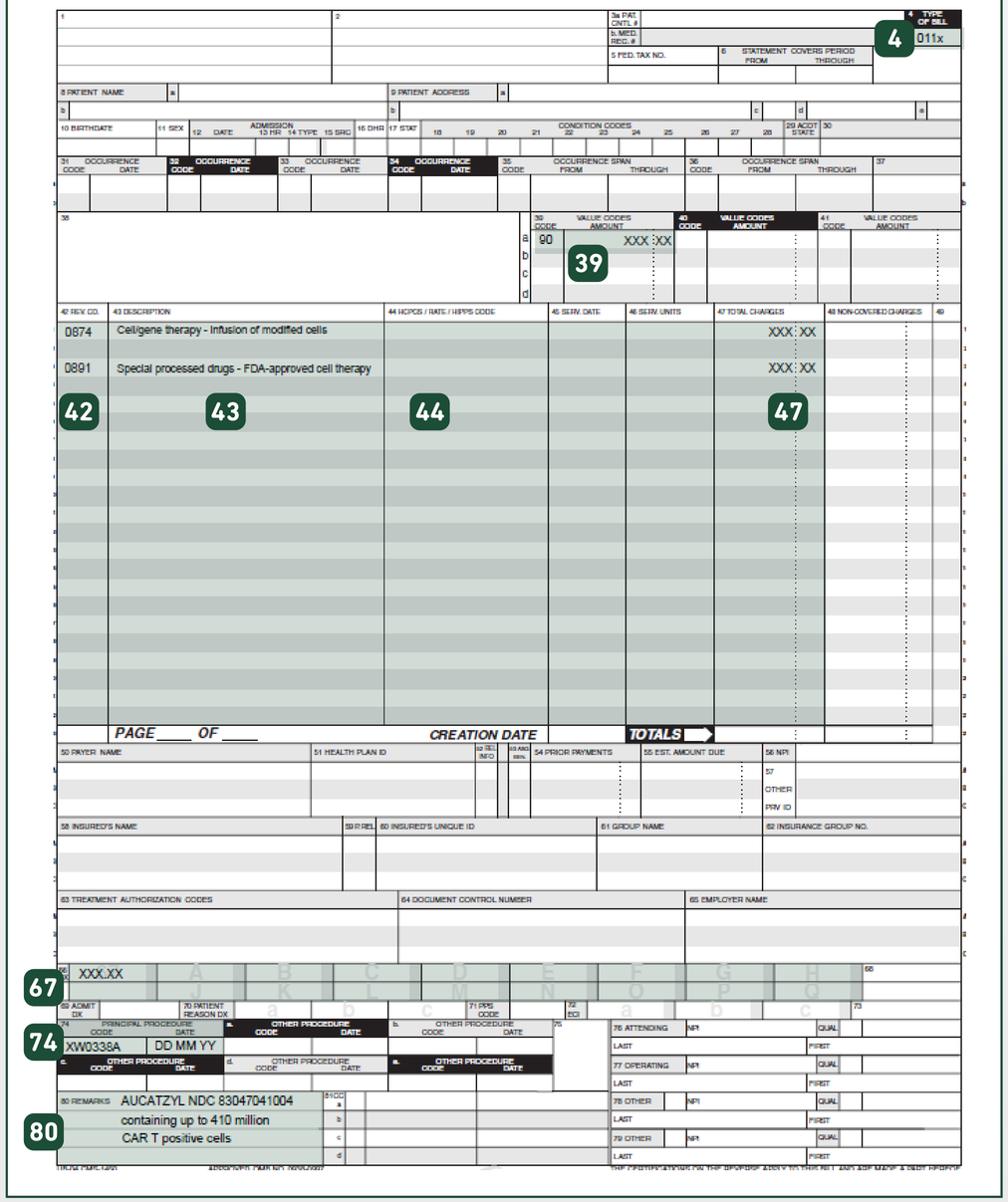
*First AUCATZYL infusion is administered 3 days (±1 day) after completion of lymphodepleting chemotherapy treatment (Day 1), allowing a minimum 48-hour washout.[1]

†Second AUCATZYL infusion is administered on Day 10 (±2 days) after the first infusion; however, a delay to the second split dose (up to Day 21) or treatment discontinuation may be required to manage toxicities. In the pivotal FELIX trial, 90% (90/100) of patients received the recommended dose of 410×10^6 +/- 25%.[1]

ATC=Authorized Treatment Center; NDC=National Drug Code.

Please see **Important Safety Information** on pages 22-24 and full **Prescribing Information, including BOXED WARNING**.

Sample CMS-1450/UB-04 claim form for inpatient hospital facilities



FL 4 Enter the appropriate type of code bill. For example, **011x** for inpatient hospital.[3]

FL 39 As needed, enter the appropriate value code(s) and corresponding value(s). For example, value code **90** can be used to report cell therapy invoice cost.[7,16]

FL 42 FL 43 Enter the appropriate revenue code, along with the corresponding description for each reported line of service. For example, **0891** for AUCATZYL and **0874** for AUCATZYL infusion.[3]
*Note: For the line with the revenue code 0891, some payers may require reporting of the 11-digit NDC number for AUCATZYL **(83047-0410-04)** in FL 43*[1]

FL 44 Some payers may require to report the appropriate HCPCS code for inpatient claims. For example, **C9399, J3490,** or **J3590** for AUCATZYL.[9]

FL 47 Enter total charges for each reported line of service.
Note: Report charges for the 2 split doses of AUCATZYL in accordance with payer requirements

FL 67 Enter the appropriate principal and other diagnosis codes.

FL 74 Enter the appropriate principal ICD-10-PCS procedure code. For example, **XW0338A** or **XW0438A** for AUCATZYL administration.[10]

FL 80 As required by payer for products with unspecified coding, enter additional drug-identifying information – for example: **AUCATZYL NDC 83047-0410-04 containing up to 410 million CAR-positive T cells.**[1]

It is important to verify specific payer billing requirements

This sample form is provided for informational purposes only. It is based on various published sources as of November 2024; it does not provide guarantee of coverage or reimbursement. The healthcare provider is responsible for confirming coding and billing requirements with each prospective patient's payer. Selecting appropriate codes and ensuring claim accuracy based on medical record documentation is the sole responsibility of the healthcare provider.
CAR=chimeric antigen receptor; CMS=Centers for Medicare and Medicaid Services; HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code.

Please see **Important Safety Information** on pages 22-24 and full **Prescribing Information, including BOXED WARNING**.

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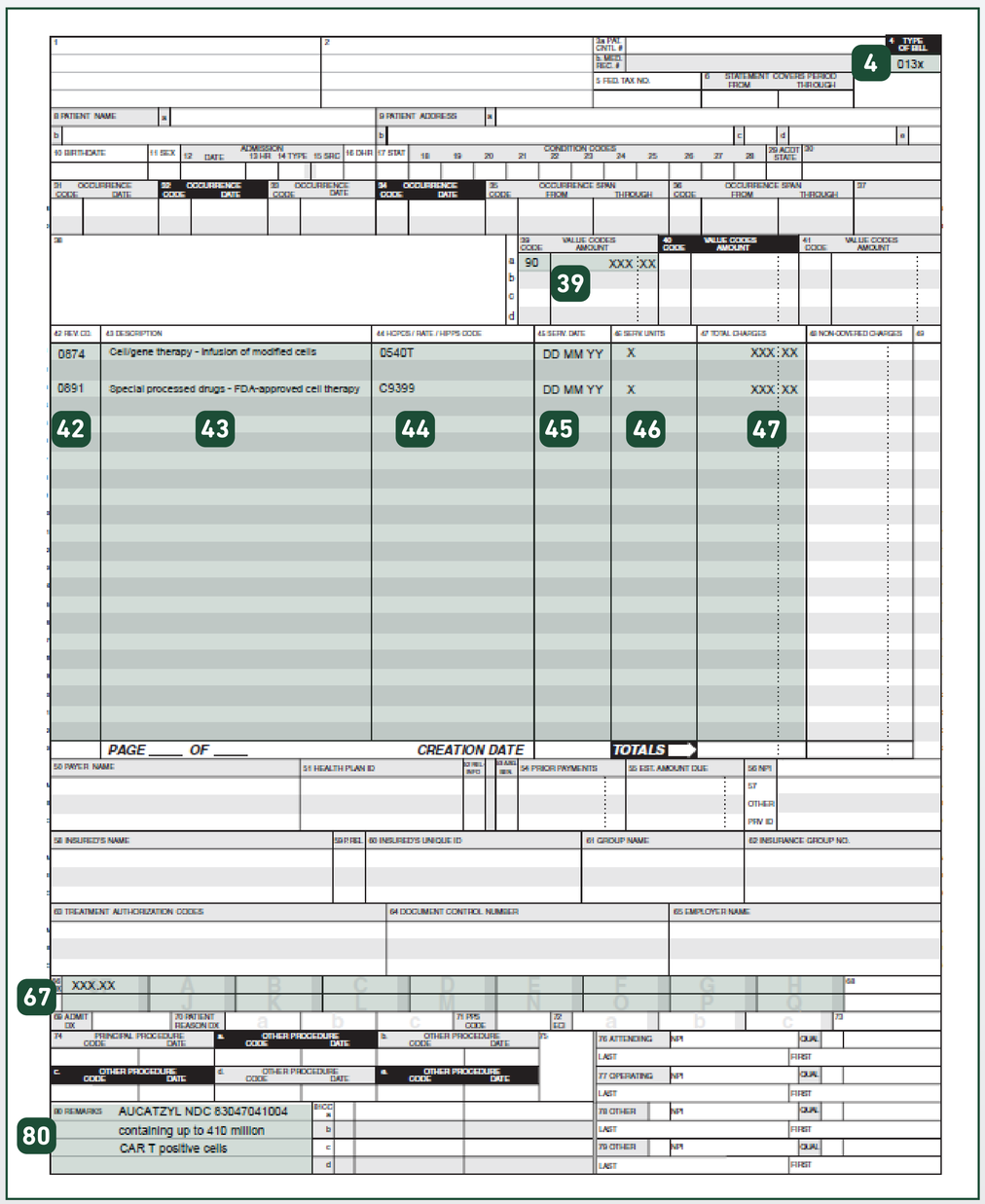
Sample CMS-1450/UB-04 claim form for outpatient hospital facilities



FL 4 Enter the appropriate type of code bill. For example, **013x** for outpatient hospital.[3]

FL 39 As needed, enter the appropriate value code(s) and corresponding value(s). For example, value code **90** can be used to report cell therapy invoice cost.[7,16]

FL 42 FL 43 Enter the appropriate revenue code, along with the corresponding description for each reported line of service. For example, **0891** for AUCATZYL and **0874** for AUCATZYL infusion.[3]
*Note: For the line with the revenue code 0891, some payers may require reporting of the 11-digit NDC number for AUCATZYL **(83047-0410-04)** in FL 43*[1]

FL 44 Enter the appropriate HCPCS codes and modifiers. For example, **C9399, J3490,** or **J3590** for AUCATZYL and **0540T** for AUCATZYL infusion.[6,9]
NOTES: In 2025, CPT Category III codes for CAR T services (eg, 0540T) will be replaced with permanent CPT Category I codes (eg, 38228).[6]
The FDA does not require a REMS for AUCATZYL.[1] For Medicare beneficiaries, contact your regional A/B MAC to confirm KX modifier reporting requirements.

FL 45 FL 46 FL 47 For each reported line of service, enter date of service, appropriate number of units of service (for example, 1 unit for C9399, J3490, or J3590), and total charges.[9]
Note: Report charges for the 2 split doses of AUCATZYL in accordance with payer requirements

FL 67 Enter the appropriate principal and other diagnosis codes.

FL 80 As required by payer for products with unspecified coding, enter additional drug-identifying information – for example: **AUCATZYL NDC 83047-0410-04 containing up to 410 million CAR-positive T cells.**[1]

It is important to verify specific payer billing requirements

This sample form is provided for informational purposes only. It is based on various published sources as of November 2024; it does not provide guarantee of coverage or reimbursement. The healthcare provider is responsible for confirming coding and billing requirements with each prospective patient's payer. Selecting appropriate codes and ensuring claim accuracy based on medical record documentation is the sole responsibility of the healthcare provider.

A/B MAC=Part A and B Medicare Administrative Contractor; CAR=chimeric antigen receptor; CMS=Centers for Medicare and Medicaid Services; CPT=Current Procedural Terminology; FDA=US Food and Drug Administration; HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code; REMS=Risk Evaluation and Mitigation Strategy.

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AutolusAssist is at your service

AUCATZYL® obecabtagene autoleucel
suspension for IV infusion

Autolus™ Assist

- Convenient way for patients, caregivers, and healthcare providers to find valuable resources and dedicated support throughout the AUCATZYL treatment journey

- Case Managers are ready to answer questions as a dedicated point-of-contact for your center staff, patients, and caregivers

- Personalized end-to-end patient support*:

  INSURANCE SUPPORT to help with BV, PA, and appeals

  TRANSPORTATION, LODGING, AND MEAL SUPPORT for eligible patients and 1 caregiver

  COPAY ASSISTANCE for eligible commercial patients

  PATIENT ASSISTANCE PROGRAM for eligible uninsured or underinsured patients

Contact AutolusAssist at 1-855-288-5227 or visit AutolusAssist.com

*Submission of the AutolusAssist Patient Support Enrollment Form is required to enroll patients in support services.
BV=benefits verification; PA=prior authorization.

Please see **Important Safety Information** on pages 22-24 and full **Prescribing Information, including BOXED WARNING**.

Your dedicated support contacts for AUCATZYL

AUCATZYL® obecabtagene autoleucel suspension for IV infusion

Autolus™ Assist

AutolusAssist Case Manager

Dedicated point of contact to assist throughout the AUCATZYL treatment journey, including scheduling and cell journey logistics support and patient support:

- Insurance support
- Transportation, lodging, and meal support
- Copay assistance
- Patient Assistance Program

Autolus Director of Payer Access Cell Therapy

Dedicated payer access and distributor order expert to assist with onsite education and provide information regarding local payers and Cardinal Health orders:

- Coverage policies
- Reimbursement trends
- Coding and billing requirements
- Cardinal Health order process options and flow

Please see **Important Safety Information** on pages 22-24 and full **Prescribing Information, including BOXED WARNING**.

Important safety information

AUCATZYL®
obecabtagene autoleucel
suspension for IV infusion

INDICATION

AUCATZYL® is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, and SECONDARY HEMATOLOGICAL MALIGNANCIES

- **Cytokine Release Syndrome (CRS) occurred in patients receiving AUCATZYL. Do not administer AUCATZYL to patients with active infection or inflammatory disorders. Prior to administering AUCATZYL, ensure that healthcare providers have immediate access to medications and resuscitative equipment to manage CRS.**
- **Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), including fatal and life-threatening reactions, occurred in patients receiving AUCATZYL, including concurrently with CRS or after CRS resolution. Monitor for neurologic signs and symptoms after treatment with AUCATZYL. Prior to administering AUCATZYL, ensure that healthcare providers have immediate access to medications and resuscitative equipment to manage neurologic toxicities. Provide supportive care and/or corticosteroids, as needed.**
- **T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies.**

WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome (CRS)

Cytokine Release Syndrome (CRS) occurred following treatment with AUCATZYL. CRS was reported in 75% (75/100) of patients including Grade 3 CRS in 3% of patients. The median time to onset of CRS was 8 days following the first infusion (range: 1 to 23 days) with a median duration of 5 days (range: 1 to 21 days). The most common manifestations of CRS included fever (100%), hypotension (35%), and hypoxia (19%).

Prior to administering AUCATZYL, ensure that healthcare providers have immediate access to medications and resuscitative equipment to manage CRS. During and following treatment with AUCATZYL, closely monitor patients for signs and symptoms of CRS daily for at least 14 days at the healthcare facility following the first infusion. Continue to monitor patients for CRS for at least 4 weeks following each infusion with AUCATZYL. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time. At the first sign of CRS, immediately evaluate the patient for hospitalization and institute treatment with supportive care based on severity and consider further management per current practice guidelines.

Neurologic Toxicities

Neurologic toxicities including Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS), which were fatal or life-threatening, occurred following treatment with AUCATZYL. Neurologic toxicities were reported in 64% (64/100) of patients, including Grade ≥ 3 in 12% of patients. The median time to onset of neurologic toxicities was 10 days (range: 1 to 246 days) with a median duration of 13 days (range: 1 to 904 days). Among patients with neurologic toxicities, the most common symptoms (> 5%) included ICANS (38%), headache (34%), encephalopathy (33%), dizziness (22%), tremor (13%), anxiety (9%), insomnia (9%), and delirium (8%).

Please see additional **Important Safety Information**, continued on pages 23 and 24, and full **Prescribing Information**.

Important safety information (cont'd)

AUCATZYL®
obecabtagene autoleucel
suspension for IV infusion

Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS)

ICANS events occurred in 24% (24/100) of patients, including Grade ≥ 3 in 7% (7/100) of patients. Of the 24 patients who experienced ICANS, 33% (8/24) experienced an onset after the first infusion, but prior to the second infusion of AUCATZYL.

The median time to onset for ICANS events after the first infusion was 8 days (range: 1 to 10 days) and 6.5 days (range: 2 to 22 days) after the second infusion, with a median duration of 8.5 days (range: 1 to 53 days).

Eighty-eight percent (21/24) of patients received treatment for ICANS. All treated patients received high-dose corticosteroids and 42% (10/24) of patients received anti-epileptics prophylactically. Prior to administering AUCATZYL, ensure that healthcare providers have immediate access to medications and resuscitative equipment to manage ICANS.

Counsel patients to seek medical attention should signs or symptoms of neurologic toxicity/ICANS occur. At the first sign of Neurologic Toxicity/ICANS, immediately evaluate patients for hospitalization and institute treatment with supportive care based on severity and consider further management per current practice guidelines.

Effect on Ability to Drive and Use Machines

Due to the potential for neurologic events, including altered mental status or seizures, patients receiving AUCATZYL are at risk for altered or decreased consciousness or coordination in the eight weeks following AUCATZYL infusion or until resolution of the neurological event by the treating physician. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, during this initial period.

Prolonged Cytopenias

Patients may exhibit cytopenias including anemia, neutropenia, and thrombocytopenia for several weeks after treatment with lymphodepleting chemotherapy and AUCATZYL. In patients who were responders to AUCATZYL, Grade ≥ 3 cytopenias that persisted beyond Day 30 following AUCATZYL infusion were observed in 71% (29/41) of patients and included neutropenia (66%, 27/41) and thrombocytopenia (54%, 22/41). Grade 3 or higher cytopenias that persisted beyond Day 60 following AUCATZYL infusion was observed in 27% (11/41) of patients and included neutropenia (17%, 7/41) and thrombocytopenia (15%, 6/41). Monitor blood counts after AUCATZYL infusion.

Infections

Severe, including life-threatening and fatal infections occurred in patients after AUCATZYL infusion. Non-COVID-19 infections of all grades occurred in 67% (67/100) of patients. Grade 3 or higher non-COVID-19 infections occurred in 41% (41/100) of patients. AUCATZYL should not be administered to patients with clinically significant active systemic infections. Monitor patients for signs and symptoms of infection before and after AUCATZYL infusion and treat appropriately. Administer prophylactic antimicrobials according to local guidelines.

Grade 3 or higher febrile neutropenia was observed in 26% (26/100) of patients after AUCATZYL infusion and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids, and other supportive care as medically indicated.

Viral reactivation, potentially severe or life-threatening, can occur in patients treated with drugs directed against B cells. There is no experience with manufacturing AUCATZYL for patients with a positive test for human immunodeficiency virus (HIV) or with active hepatitis B virus (HBV) or active hepatitis C virus (HCV). Perform screening for HBV, HCV and HIV in accordance with clinical guidelines before collection of cells for manufacturing.

Please see additional **Important Safety Information**, continued on page 24, and full **Prescribing Information**.

Important safety information (cont'd)

AUCATZYL®
obecabtagene autoleucel
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Hypogammaglobulinemia

Hypogammaglobulinemia and B-cell aplasia can occur in patients after AUCATZYL infusion. Hypogammaglobulinemia was reported in 10% (10/100) of patients treated with AUCATZYL including Grade 3 events in 2 patients (2%).

Immunoglobulin levels should be monitored after treatment with AUCATZYL and managed per institutional guidelines including infection precautions, antibiotic or antiviral prophylaxis, and immunoglobulin replacement.

The safety of immunization with live viral vaccines during or following treatment with AUCATZYL has not been studied. Vaccination with live viral vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy treatment, during AUCATZYL treatment, and until immune recovery following treatment with AUCATZYL.

Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS)

HLH/MAS including fatal and life-threatening reactions occurred after treatment with AUCATZYL. HLH/MAS was reported in 2% (2/100) of patients and included Grade 3 and Grade 4 events with a time of onset at Day 22 and Day 41, respectively. One patient experienced a concurrent ICANS events after AUCATZYL infusion and died due to sepsis with ongoing HLH/MAS that had not resolved. Administer treatment for HLH/MAS according to institutional standards.

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis, may occur due to dimethyl sulfoxide (DMSO), an excipient used in AUCATZYL. Observe patients for hypersensitivity reactions during and after AUCATZYL infusion.

Secondary Malignancies

Patients treated with AUCATZYL may develop secondary malignancies. T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies. Mature T cell malignancies, including CAR-positive tumors, may present as soon as weeks following infusion, and may include fatal outcomes. Monitor lifelong for secondary malignancies. In the event that a secondary malignancy occurs, contact Autolus at 1-855-288-5227 for reporting and to obtain instructions on the collection of patient samples for testing.

Adverse Reactions

The safety of AUCATZYL was evaluated in the FELIX study in which 100 patients with relapsed or refractory B-cell acute lymphoblastic leukemia (B-ALL) received AUCATZYL at a median dose of 410 × 10^6 CD19 CAR-positive viable T cells (range: 10 to 480 × 10^6 CD19 CAR-positive viable T cells with 90% of patients receiving the recommended dose of 410 x 10^6 +/- 25%).

The most common serious adverse reactions of any Grade (incidence ≥ 2%) included infections-pathogen unspecified, febrile neutropenia, ICANS, CRS, fever, bacterial infectious disorders, encephalopathy, fungal infections, hemorrhage, respiratory failure, hypotension, ascites, HLH/MAS, thrombosis and hypoxia. Nine patients (9%) experienced fatal adverse reactions which included infections (sepsis, pneumonia, peritonitis), ascites, pulmonary embolism, acute respiratory distress syndrome, HLH/MAS and ICANS. Of the 9 patients, five patients who died from infections had pre-existing and ongoing neutropenia prior to receiving bridging therapy, lymphodepletion chemotherapy treatment and/or AUCATZYL.

Please see full **Prescribing Information, including BOXED WARNING** and Medication Guide.

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