



(onasemnogene abeparvovec-brve)
suspension for intrathecal injection

HCP Coding and Billing Guide



INDICATION

ITVISMA is indicated for the treatment of spinal muscular atrophy (SMA) in adult and pediatric patients 2 years of age and older with confirmed mutation in *survival motor neuron 1 (SMN1)* gene.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: Serious Liver Injury

Acute serious liver injury can occur with ITVISMA. Hepatotoxicity, with elevated alanine transaminase (ALT) and/or aspartate transaminase (AST) levels, has occurred with ITVISMA. Patients with preexisting hepatic impairment or acute hepatic viral infection may be at higher risk of liver injury. To mitigate potential aminotransferase elevations, administer systemic corticosteroid before and after ITVISMA injection. Prior to ITVISMA injection, assess liver function by clinical examination and laboratory testing. Continue to monitor liver function for at least 3 months after ITVISMA administration, and at other times as clinically indicated. In case hepatic injury is suspected, further testing is recommended. Promptly consult with a gastroenterologist or hepatologist, as necessary.

HCP, health care professional.

Please see additional Important Safety Information on page 12 and [click here](#) for full Prescribing Information, including Boxed WARNING.

Overview

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HCPCS Code

CPT® Codes for
Administration and
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An overview of this guide

This guide has been developed to assist you in billing and coding for ITVISMA® (onasemnogene abeparvovec-brve) where health plans provide coverage for ITVISMA as part of the medical benefit. As a result, ITVISMA is available to purchase from CuraScript SD® for buy-and-bill treatment centers and through a limited network of specialty pharmacies.

ITVISMA Distribution

BUY AND BILL

Ordered from
CuraScript SD®
Phone: **1-866-263-8464**

LIMITED NETWORK SPECIALTY PHARMACIES

Novartis Pharmaceuticals Corporation has partnered with select specialty pharmacies, including Accredo® Specialty Pharmacy, Orsini Specialty Pharmacy, and Axium/Farmacia Doral Specialty Pharmacy (Puerto Rico only), to support ITVISMA.

Please contact your Novartis Regional Account Associate Director (RAAD) or Novartis Patient Support™ should you have any questions.

This guide provides codes^a for

Submitting a claim
to a patient's health plan
for reimbursement

**Injection codes for
ITVISMA^b**

**Lab testing
and diagnosis**

^aCodes provided in this guide may be subject to change. Please be sure to confirm the accuracy of all codes when submitting a claim.

^bCodes related to other aspects of SMA or its comorbidities are not included.



For live support about ordering, access and reimbursement, or coding and billing, please contact your **RAAD** with any questions you have



Dosing and NDC designation

The recommended dose of ITVISMA® (onasemnogene abeparvovec-brve) is 1.2×10^{14} vector genomes (vg) for adult and pediatric patients 2 years of age and older.¹

The National Drug Code (NDC) numbers for ITVISMA are 71894-200-**01** for a single-dose vial and 71894-200-**02** for a carton.¹ Please confirm the appropriate NDC number to use for billing with the patient's health plan.

HCPCS code

ITVISMA is billed under an HCPCS J-code. Effective July 1, 2026, the Centers for Medicare & Medicaid Services assigned ITVISMA the following permanent J-code: J3405.² HCPCS J-codes are used for items and supplies and non-physician services not covered by Current Procedural Terminology-4 (CPT-4) codes. J-codes are recommended when filling out and submitting a CMS-1450/UB-04 or CMS-1500 form.³



Appropriate codes may vary by setting of care and by payor – providers are encouraged to reach out to payors to confirm appropriate coding procedures

HCPCS code for ITVISMA injection²

DESCRIPTION	CODE
Injection, onasemnogene abeparvovec-brve, per treatment	J3405

HCPCS, Healthcare Common Procedure Coding System.

Utilization of the J-code is required when billing for ITVISMA. Please ensure the billing system at your organization has been updated accordingly to support accurate coding and billing processes.

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CPT® codes for administration and observation

ITVISMA® (onasemnogene abeparvovec-brve) is administered via a single-dose intrathecal injection.¹ The following CPT® codes may be useful when coding and billing for ITVISMA treatment. **Please note that these codes do not include office visits for diagnosis and prescribing of medication.** Appropriate codes can vary by setting of care, patient, and payor. It is the provider's responsibility to determine the appropriate health care setting and to submit true and correct claims for actual products and services rendered. Please check with the payor to verify codes and special billing requirements.

Remember, billing for ITVISMA should be done separately and only if your institution is buying and billing. For facilities that choose to buy and bill, please refer to the section on HCPCS codes in this guide.

CPT® codes for ITVISMA injection⁴

DESCRIPTION	CODE
DRUG ADMINISTRATION AND IMAGING PROCEDURE/GUIDANCE	
Chemotherapy administration, into central nervous system (eg, intrathecal), requiring and including spinal puncture	96450
Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter)	62272
Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter); with fluoroscopic or CT guidance	62329
Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinal diagnostic or therapeutic injection procedures (epidural or subarachnoid)	77003
Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision, and interpretation	76942
CT guidance for needle placement (eg, biopsy, aspiration, injection, localization device), including radiological supervision and interpretation	77012

CT, computed tomography.

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CPT® codes for administration and observation (cont)

CPT® codes for ITVISMA® (onasemnogene abeparvovec-brve) injection⁴ (cont)

DESCRIPTION	CODE
ANESTHESIA	
Anesthesia for procedures in lumbar region (including diagnostic or therapeutic lumbar punctures)	00635
Anesthesia for patient of extreme age, younger than 1 year and older than 70 years (list separately in addition to code for primary anesthesia procedure)	99100
MODERATE (CONSCIOUS) SEDATION	
Coding is based on total intra-service time and the health care professional who is performing the procedure	99151-99153, 99155-99157
OUTPATIENT HOSPITAL OBSERVATION STATUS	
Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level, moderate level, or high level of medical decision making	99221-99223
Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and straightforward or low level, moderate level, or high level of medical decision making	99234-99236
Inpatient hospital care or observation discharge day management time of a patient on the encounter date	99238-99239



You may need these codes regardless of the distribution method for ITVISMA

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CPT® codes for testing

Insurance providers may require the following tests prior to injection with ITVISMA® (onasemnogene abeparvovec-brve)

- SMA Diagnostic Test to confirm *SMN1* deletion or historical documentation of prior test
- Anti-AAV9 Antibody Test

Monitoring is required prior to and post-injection with ITVISMA¹

Assess liver function (clinical exam, AST, ALT, albumin, prothrombin time, PTT, INR, and total bilirubin), obtain creatinine and complete blood count (including hemoglobin and platelet count), and perform baseline testing for the presence of anti-AAV9 antibodies. Post-injection, monitor liver function (AST, ALT, total bilirubin) weekly for a month (or longer) after ITVISMA injection and during the corticosteroid taper period (28 days or longer if needed). If the patient is clinically stable with unremarkable findings (normal clinical exam, total bilirubin, and ALT and AST levels below 2 × ULN) at the end of the corticosteroid taper period, continue to monitor liver function every other week for another month. Monitor platelet counts weekly for the first month and as clinically indicated until platelet counts return to baseline, as described in the Prescribing Information.

Novartis covers the cost for the following tests as part of the Novartis Laboratory Testing Program

- SMA Diagnostic Test
- Anti-AAV9 Antibody Test

If you have any questions regarding the Novartis Laboratory Testing Program, please contact Novartis Patient Support at **1-855-441-4363, Monday through Friday (8 AM to 8 PM ET)**, for additional assistance.

Additional recommended testing codes related to treatment with ITVISMA⁵

TEST	CODE ^a
AST	84450
ALT	84460
CBC (includes differential and platelets)	85025
Bilirubin, total	82247
Prothrombin time (includes INR)	85610
Creatinine	82565
Serum albumin	82040
Thromboplastin time, partial	85730

^aA specific test code may be required in addition to the CPT® code. Please confirm which codes are required for your preferred laboratory.



Your **RAAD** can answer questions you may have about lab tests, but if there are further questions, please contact Novartis Patient Support at **1-855-441-4363**

AAV9, adeno-associated virus serotype 9; ALT, alanine aminotransferase; AST, aspartate aminotransferase; CBC, complete blood count; INR, international normalized ratio; PTT, partial thromboplastin time; ULN, upper limit of normal.

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Revenue codes

Revenue codes should be used primarily on the UB-04 Form to identify the department or type of service where the charge occurred within the hospital setting.

Revenue codes for outpatient hospital-based facilities⁶

DESCRIPTION	CODE
Anesthesia, general classification	0370
Drugs requiring detailed coding	0636
Recovery room, general classification: permits identification of particular services, if necessary	0710

ICD-10-CM codes

A diagnosis of SMA is required by health plans to substantiate the medical necessity of ITVISMA[®] (onasemnogene abeparvovec-brve). Please refer to the following codes when documenting a patient's diagnosis.⁷

ICD-10-CM codes for SMA⁷

CONDITION	CODE
Infantile SMA, type 1 (Werdnig-Hoffmann)	G12.0
Other inherited SMA <ul style="list-style-type: none"> • Adult form SMA • Childhood form, type 2 SMA • Distal SMA • Juvenile form, type 3 SMA (Kugelberg-Welander) • Progressive bulbar palsy of childhood (Fazio-Londe) • Scapuloperoneal form SMA 	G12.1
Other specified SMAs and related syndromes	G12.8
SMA, unspecified	G12.9
Progressive SMA	G12.25

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

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Submitting forms and claims

When submitting claims for ITVISMA® (onasemnogene abeparvovec-brve), you will most likely be required to fill out the CMS-1450/UB-04 or CMS-1500 Form. The following suggestions can help with the claim process:

- Ensure the following information is accurate
 - Patient name and date of birth
 - Patient or patient's parent/legal guardian name, ID number, address
 - Prescriber name and National Provider Identifier (NPI)
 - HCPCS code
 - ICD-10-CM code
- Confirm that your patient's medical records support the diagnosis and procedure codes
- Include a brief description of the medical reason for treatment and why ITVISMA is medically necessary
- Enter the prior authorization number provided by your patient's insurance carrier



Please contact your **RAAD** with any questions you have about ITVISMA coding and billing

Frequently asked questions



How to Order

1. How do I order ITVISMA® (onasemnogene abeparvovec-brve)?

For assistance with ordering and billing, please contact your RAAD, who will be able to provide you with materials and information to address the specific needs of your office.

ITVISMA may be ordered in 2 ways:

- **Purchase directly from CuraScript SD®.** Order ITVISMA, and CuraScript SD® will drop-ship directly to your treatment center pharmacy
- **Order through one of the limited network specialty pharmacies, including:**
 - Accredo® Specialty Pharmacy
Phone: **1-800-803-2523**
 - Orsini Specialty Pharmacy
Phone: **1-800-697-5048**
 - Axiom/Farmacia Doral Specialty Pharmacy (Puerto Rico only)
Phone: **1-844-355-4191**

Novartis does not recommend or require the use of any particular pharmacy.

The specialty pharmacy will order ITVISMA, bill your patient's insurance, and ship product to your treatment center pharmacy.

Novartis Patient Support can help verify which specialty pharmacy is in-network with the patient's insurance policy to ensure a seamless and efficient ordering process.

Insurance Coverage and Billing

2. Is ITVISMA covered under an inpatient diagnosis-related group (DRG) for billing?

- ITVISMA is intended to be administered in an outpatient setting under the direction of health care professionals
- Please contact the patient's health plan as needed for additional clarity

3. Does Novartis cover the cost of the diagnostic testing?

The Novartis Laboratory Testing Program covers the cost of the following diagnostic lab tests:

- SMA Diagnostic Test
- Anti-AAV9 Antibody Test

To learn more, please contact your RAAD, or Novartis Patient Support.

4. How do I bill for ITVISMA through state Medicaid?

Each Medicaid plan will vary in their coverage policies. Please contact your RAAD for a detailed discussion of state policies.

5. How do I bill for ITVISMA through Medicare?

Claims for ITVISMA should be submitted to your local Medicare Administrative Contractor (MAC). Contact the MAC directly to confirm the appropriate coding process as they will vary by payor and by MAC.

6. How does insurance reimburse for ITVISMA injection?

For buy-and-bill treatment centers, the cost of ITVISMA should be billed separately from services related to its treatment. Please refer to the CPT® and hospital revenue codes in this guide for more information that will help you when billing for injection of ITVISMA.

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Indication and Important Safety Information

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WARNINGS AND PRECAUTIONS

Thrombocytopenia

Transient decreases in platelet counts were observed within the first week after ITVISMA administration. Monitor platelet counts before ITVISMA injection and on a regular basis afterwards until platelet counts return to baseline.

Peripheral Sensory Neuropathy

Peripheral sensory neuropathy has occurred with ITVISMA administration with onset seen at approximately 3 weeks post-injection in clinical studies. Consider complete neurologic evaluation and other testing and/or symptom management based on the patient's clinical presentation.

Thrombotic Microangiopathy

Thrombotic microangiopathy (TMA) may occur with ITVISMA administration and can result in life-threatening or fatal outcomes. Monitor platelet counts on a regular basis following ITVISMA injection, as well as signs and symptoms of TMA. Consult a hematologist and/or nephrologist immediately to manage TMA as clinically indicated.

Elevated Cardiac Troponin I

Increases in cardiac troponin I levels have occurred following ITVISMA administration. Consider cardiac evaluation after ITVISMA administration and consult a cardiologist as needed.

AAV Vector Integration and Risk of Tumorigenicity

There is a theoretical risk of tumorigenicity due to integration of AAV vector DNA into the genome. The clinical relevance of individual integration events is unknown, but it is acknowledged that individual integration events could potentially contribute to a risk of tumorigenicity. Report cases of tumor development in patients who received ITVISMA to Novartis Gene Therapies, Inc. at 1-833-828-3947.

ADVERSE EVENTS

The most common adverse reactions that occurred in $\geq 2\%$ of patients treated with ITVISMA were upper respiratory tract infection, pyrexia, upper gastrointestinal symptoms, hepatic enzymes increased, headache, dizziness, pain in extremity, thrombocytopenia, and sensory disturbance.

Please [click here](#) for full Prescribing Information.



For live support about ordering, access and reimbursement, or coding and billing, please contact your **RAAD or Novartis Patient Support**, with any questions you may have

References: **1.** ITVISMA Prescribing information. Novartis Gene Therapies, Inc. **2.** Centers for Medicare and Medicaid Services. Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Determinations. Accessed April 16, 2026. <https://www.cms.gov/files/document/2026-hcpcs-application-summary-quarter-1-2026-drugs-biologicals.pdf> **3.** Centers for Medicare and Medicaid Services. Billing and coding: hospital outpatient drugs and biologicals under the outpatient prospective payment system (OPPS). Updated December 26, 2024. Accessed April 28, 2026. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55913&ver=9&bc=0> **4.** American Medical Association. *2026 AMA CPT Professional*. American Medical Association; 2025. Accessed April 16, 2026. <https://aapc.vitalsource.com/reader/books/A25BPL0007> **5.** Centers for Medicare and Medicaid Services. Medicare claims processing manual: chapter 16–laboratory services. Published January 8, 2026. Accessed April 16, 2026. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c16.pdf> **6.** Centers for Medicare and Medicaid Services. CMS manual system: pub 100-04 Medicare claims processing. Published July 10, 2009. Accessed April 16, 2026. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1767CP.pdf> **7.** Centers for Medicare and Medicaid Services. ICD-10. Updated April 1, 2026. Accessed April 16, 2026. <https://www.cms.gov/medicare/coding-billing/icd-10-codes>

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