AURLUMYN™
(iloprost) Injection

AURLUMYN Reimbursement and Coding Guide

Product Information and Diagnosis Codes for AURLUMYN

Product information	
NDC to be submitted on the claim[1]	**How supplied**[1]
11-digit Carton and Vial: 83226-2001-01 **10-digit Carton and Vial:** 83226-2001-1	Carton containing one clear, colorless sterile solution supplied as 100 mcg per mL in a single-dose glass vial.

Product J-code	
Coding system	**Code and description**
HCPCS[2]	J1749 Injection, iloprost, 0.1 mcg

Patient diagnosis codes				
Coding system		**Initial encounter**	**Subsequent encounter**	**Sequela**
ICD-10-CM[3-5]	**Codes and descriptions for frostbite with tissue necrosis of fingers/toes**			
	Frostbite with tissue necrosis of **right finger(s)**	T34.531A	T34.531D	T34.531S
	Frostbite with tissue necrosis of **left finger(s)**	T34.532A	T34.532D	T34.532S
	Frostbite with tissue necrosis of **unspecified finger(s)**	T34.539A	T34.539D	T34.539S
	Frostbite with tissue necrosis of **right toe(s)**	T34.831A	T34.831D	T34.831S
	Frostbite with tissue necrosis of **left toe(s)**	T34.832A	T34.832D	T34.832S
	Frostbite with tissue necrosis of **unspecified toe(s)**	T34.839A	T34.839D	T34.839S
	Codes and descriptions for superficial frostbite of fingers/toes			
	Superficial frostbite of **right finger(s)**	T33.531A	T33.531D	T33.531S
	Superficial frostbite of **left finger(s)**	T33.532A	T33.532D	T33.532S
	Superficial frostbite of **unspecified finger(s)**	T33.539A	T33.539D	T33.539S
	Superficial frostbite of **right toe(s)**	T33.831A	T33.831D	T33.831S
	Superficial frostbite of **left toe(s)**	T33.832A	T33.832D	T33.832S
	Superficial frostbite of **unspecified toe(s)**	T33.839A	T33.839D	T33.839S

HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, National Drug Code.

Please see Indications and Important Safety Information on page 7 and scan QR code on page 8 for full Prescribing Information for AURLUMYN.

SERB Pharmaceuticals

ICD-10-PCS codes anticipated
Currently, there are no approved ICD-10-PCS codes for AURLUMYN. However, they are anticipated by October 1, 2025. Until these codes are available, hospitals administering AURLUMYN can use a nonspecific ICD-10-PCS code for an unspecified therapeutic substance such as: **3E033GC** (Introduction of Other Therapeutic Substance into Peripheral Vein, Percutaneous Approach)[6] **-OR-** **3E043GC** (Introduction of Other Therapeutic Substance into Central Vein, Percutaneous Approach)[7]

Patient diagnosis codes (continued)	
Coding system	**Codes and descriptions**
MS-DRG[3,8]	**901** Wound debridements for injuries with MCC
	902 Wound debridements for injuries with CC
	904 Skin grafts for injuries with CC/MCC
	906 Hand procedures for Injuries
	907 Other OR procedures for injuries with MCC
	908 Other OR procedures for injuries with CC
	909 Other OR procedures for injuries without CC/MCC
	922 Other injury, poisoning and toxic effect diagnoses with MCC
	923 Other injury, poisoning and toxic effect diagnoses without MCC

DISCLAIMER:

The publicly available information provided in this Reimbursement and Coding Guide is intended for informational purposes only and does not constitute legal, medical, or professional advice. It is designed to assist healthcare providers in understanding reimbursement policies, coding guidelines, and billing procedures. However, it is not exhaustive, and healthcare providers are advised to consult the most current official sources, including but not limited to payer policies, government regulations, and relevant professional organizations, for the most up-to-date and accurate information. It is not intended to guarantee, increase, or maximize reimbursement by any payer.

Healthcare providers are responsible for ensuring compliance with all applicable federal, state, and local laws, regulations, and payer-specific policies when submitting claims for reimbursement. Individual coding decisions should be based upon diagnosis and treatment of individual patients. SERB does not warrant, promise, guarantee, or make any statement that the codes supplied in this guide are appropriate or that the use of this information will result in coverage or payment for treatment using AURLUMYN or that any payment received will cover providers' costs.

This guide does not guarantee reimbursement or the success of any claim submission. Reimbursement decisions are made solely by the payer, and healthcare providers are advised to seek guidance from the payer directly to confirm coverage and payment policies. Before any claims or appeals are submitted, hospitals and physicians should review official payer instructions and requirements, should confirm the accuracy of their coding or billing practices with these payers, and should use independent judgment when selecting codes that most appropriately describe the services or supplies furnished to a patient. It is the provider's responsibility to determine and document that the services provided are medically necessary and that the site of service is appropriate.

Providers are encouraged to contact third-party payers for specific information on their coverage, coding, and payment policies. Please consult with your legal counsel or reimbursement specialists.

CC, complication or comorbidity; ICD-10-PCS, International Classification of Diseases, 10th Revision, Procedure Coding System; MCC, major complication or comorbidity; MS-DRG, Medicare severity diagnosis-related group; OR, operating room.

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Reimbursement and Coding Guide

Overview of New Technology Add-on Payments (NTAPs)

NTAP status[9,10]

NTAP eligibility for AURLUMYN is pending and anticipated in October 2025. If granted, the NTAP designation is expected to last 2 to 3 years.

NTAP payments—The NTAP is a program from the Centers for Medicare & Medicaid Services (CMS) that provides extra payments to hospitals for using new medical technologies, drugs, or devices that qualify.[9]

- NTAPs are limited to the lesser of 65% of the costs of the technology, or 65% of the amount by which the costs of the case exceed the standard MS-DRG payment[9]

Overview of Outlier Payments

Outlier claim status[11]

As soon as AURLUMYN is available, hospitals may qualify for outlier payments for AURLUMYN claims from Medicare.

Outlier payments—payments for which a hospital is eligible for after incurring extraordinarily high costs.[11]

- A case must have costs **above a fixed-loss cost threshold amount**[11]
  - Thresholds are dollar amounts by which the costs of a case must exceed payments in order to qualify. The threshold for 2025 is $46,152[11,12]
- Relevant costs, treatment factors, and calculations are typically submitted to CMS in spreadsheet format[11,13]

Outlier payments may help with AURLUMYN-associated costs until the period of NTAP eligibility begins and after that period expires.[11]

MS-DRG, Medicare severity diagnosis-related group.

Hospital Outlier Payment Backgrounder

Section 1886(d)(5)(A) of the Social Security Act provides for Medicare payments to participating hospitals in addition to the basic prospective payments for cases incurring extraordinarily high costs.[11]

To qualify for outlier payments, a case must have costs above a fixed-loss cost threshold amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for outliers).[11]

Cost outliers apply to all inpatient facilities, including but not limited to[14-18]:

- Acute care facilities
- Inpatient rehabilitation facilities
- Inpatient psychiatric facilities
- Long-term care facilities
- Veterans Affairs-related claims

Billing

To bill an outlier, there must be days of utilization (Medicare benefit days) available to the beneficiary.[19,20]

Coding

To properly code an outlier claim, the provider must know the Covered, Non-covered, Co-insurance, and Lifetime Reserve (LTR) days available. It is only after all days have been used that benefits are exhausted.[19,20]

Two pieces of information are needed to determine if an outlier should be coded[11]:

1. Total covered charges
2. Inpatient Prospective Payment System (IPPS) threshold amount

Payment[11-13,21]

For a case to qualify for outlier payment, it must have ***total*** costs above a fixed-loss cost threshold amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for outliers). The outlier fixed-loss threshold for FY 2025, which runs from October 1, 2024, through September 30, 2025, is $46,152. CMS pays 80% of costs exceeding DRG payment.

Key factors that will impact qualification for outlier payment are:

- DRG assignment
- Charges reported on the claim
- Your hospital's cost-to-charge ratio

Geography, indirect medical education (IME) factors, and disproportionate share hospital (DSH) factors also impact calculation. Hospitals should determine if a claim should be submitted as an outlier. The Inpatient PPS Web Pricer is available to help estimate payment.

Click or scan to access the Inpatient PPS Web Pricer

Medicare Administrative Contractors (MACs)

Some of the MACs may also provide guidance regarding outlier claim information and submission instructions on their websites:

- First Coast Service Options (FL, Puerto Rico, US Virgin Islands)
- Novitas Outlier Claim Information and Submission Instructions (AR, CO, DC, DE, LA, MD, MS, NJ, NM, PA, OK, TX)
- Noridian Inpatient PPS Billing for Cost Outlier (AK, AZ, CA, HI, ID, MT, ND, NV, OR, SD, UT, WA, WY, American Samoa, Guam, Northern Mariana Islands)
- Palmetto Inpatient PPS Outlier Billing (AL, GA, NC, SC, VA, TN, WV)
- NGS does not provide specific information on their website but provides the link to the Inpatient PPS Web Pricer on the CMS website (CT, IL, MA, ME, MN, NH, NY, RI, VT, WI)
- WPS provides no supplemental information (IA, IN, KS, MI, MO, NE)
- CGS provides no supplemental information (KY, OH)

Click or scan to learn more about MACs

CGS, CGS Administrators, LLC; DRG, diagnosis-related group; NGS, National Government Services, Inc; WPS, Wisconsin Physicians Service Government Health Administrators.

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Hospital Outlier Payment Backgrounder *(continued)*

Outlier payment calculation example[13]

The following example simulates the outlier payment for a case at a hospital in the San Francisco, California CBSA, which is a large urban area. The patient was discharged on/after October 1, 2006, and the hospital incurred Medicare-approved charges of $150,000. The DRG assigned to the case was 498. The hospital is 100% Federal for capital payment purposes.

Note: This spreadsheet is only an estimate of payment. It is not to be relied upon for exact payment.

Table of operating values used in calculation	
DRG 498 Relative Weight	2.9896
Labor-related	$3,397.52
Nonlabor-related	$1,476.97
San Francisco CBSA Wage Index	1.5419
Cost of Living Adjustment (COLA)	1
IME Operating Adjustment Factor	0.0744
DSH Operating Adjustment Factor	0.1413
Labor-related portion	0.697
Nonlabor-related portion	0.303
Operating Cost-to-Charge Ratio	0.38

Table of capital values used in calculation	
DRG 498 Relative Weight	2.9896
Federal Capital Rate	$427.03
Large Urban Add-on	1.03
San Francisco CBSA GAF	1.3452
Cost of Living Adjustment	1
IME Operating Adjustment Factor	0.0243
DSH Operating Adjustment Factor	0.0631
Capital Cost-to-Charge Ratio	0.04

Other factors	
Billed Covered Charges	$150,000
Fixed Loss Outlier Threshold	$24,485
Marginal Cost Factor	0.8

Step 1: Determine federal operating payment with IME and DSH

Federal Rate for Operating Costs =

(DRG Relative Weight x ((Labor-Related Large Urban Standardized Amount x San Francisco CBSA Wage Index) + (Nonlabor-Related National Large Urban Standardized Amount x Cost of Living Adjustment)) x (1 + IME + DSH))

Federal Operating Payment With IME and DSH = $24,407.58

Step 2: Determine federal capital payment with IME and DSH

Federal Rate for Capital Costs =

((DRG Relative Weight x Federal Capital Rate x Large Urban Add-on x Geographic Cost Adjustment Factor x COLA) x (1 + IME + DSH))

Federal Capital Payment With IME and DSH = $1,923.47

Step 3: Determine operating and capital costs

Operating Costs =

Billed Charges x Operating Cost-to-Charge Ratio

Operating Costs = $57,000

Capital Costs =

Billed Charges x Capital Cost-to-Charge Ratio

Capital Costs = $6,000

CBSA, core basic statistical area; DRG, diagnosis-related group; DSH, disproportionate share hospital; GAF, geographic adjustment factor; IME, indirect medical education.

Hospital Outlier Payment Backgrounder *(continued)*

Outlier payment calculation example[13] *(continued)*

Step 4: Determine operating and capital outlier threshold

A. Operating CCR to Total CCR =
Operating CCR / (Operating CCR + Capital CCR)
Operating CCR to Total CCR = 0.9048

B. Capital CCR to Total CCR =
Capital CCR / (Operating CCR + Capital CCR)
Capital CCR to Total CCR = 0.0952

C. Operating Outlier Threshold =
((Fixed Loss Threshold x (Labor-related portion x San Francisco CBSA Wage Index) + Nonlabor-related portion)) x Operating CCR to Total) + Federal Payment With IME and DSH
Operating Outlier Threshold = $54,929.28

D. Capital Outlier Threshold =
(Fixed Loss Threshold x Geographic Adjustment Factor x Large Urban Add-on x Capital CCR to Total CCR) + Federal Payment With IME and DSH
Capital Outlier Threshold = $5,153.16

Step 5: Determine operating and capital outlier payment amount

A. Determine if Total Costs are greater than Combined Threshold =
(if (Operating Costs + Capital Costs) > (Operating Threshold + Capital Threshold))
Determine if Total Costs are greater than Combined Threshold = TRUE, Continue With Next Step

B. Operating Outlier Payment =
(Operating Costs - Operating Outlier Threshold) x Marginal Cost Factor
Operating Outlier Payment = $1,656.58

C. Capital Outlier Payment =
(Capital Costs - Capital Outlier Threshold) x Marginal Cost Factor
Note: If Capital Outlier Payment Amount is Negative, we default this amount to 0
Capital Outlier Payment = $677.47

Click or scan to access the spreadsheet in the downloads section
Spreadsheet can be located in the downloads section at:
https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier

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CBSA, core basic statistical area; CCR, cost-to-charge ratio; DSH, disproportionate share hospital; IME, indirect medical education.

Indications and Important Safety Information

INDICATIONS AND USAGE

AURLUMYN is a prostacyclin mimetic indicated for the treatment of severe frostbite in adults to reduce the risk of digit amputations. Effectiveness was established in young, healthy adults who suffered frostbite at high altitudes.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- AURLUMYN may cause symptomatic hypotension. Correct hypotension prior to administration of AURLUMYN. Monitor vital signs while administering AURLUMYN.

Adverse Reactions

- Adverse events reported with the use of intravenous (IV) iloprost in patients with frostbite include headache, flushing, palpitations/tachycardia, nausea, vomiting, dizziness, and hypotension.

Use in Specific Populations

- Advise women not to breastfeed during treatment with AURLUMYN.
- The safety and efficacy of AURLUMYN in pediatric patients have not been established.
- Dosage adjustment is recommended in patients with moderate or severe hepatic impairment.
- In patients with eGFR <30 mL/min, dosage adjustment can be considered based on tolerability. The effect of dialysis on the clearance of AURLUMYN has not been evaluated.

To report suspected adverse reactions, contact BTG at 1-877-377-3784 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References

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