

AURLUMYN Ordering, Pricing, and Distribution Product Fact Sheet

AURLUMYN—the first and only FDA-approved treatment option for severe frostbite in adults to reduce the risk of digit amputations^{1,2}

Effectiveness was established in young, healthy adults who suffered frostbite at high altitudes

Established name: Iloprost injection, for intravenous use¹

Website: AURLUMYN.com

Supplied and marketed by: BTG International Inc., a SERB Pharmaceuticals Company | SERB.com

24-hour medical information: 1-877-377-3784 | serbmedinfo@serb.com

Customer service: 1-844-293-0007



NDC 50633-340-01

Product information and pricing				
Product information	NDC number for ordering ¹	How supplied ¹	Sale quantity ¹	
	11-digit Carton and Vial: 50633-0340-01	sterile solution supplied as 100 mcg		
	10-digit Carton and Vial: 50633-340-01			
Pricing	WAC ³ : \$5500 per vial			
	NOTE: AURLUMYN pricing as of October 1, 2025. Please confirm the current pricing wit your SERB Representative.		g with	

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.

FDA, US Food and Drug Administration; NDC, National Drug Code; WAC, wholesale acquisition cost.





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New Technology Add-On Payment (NTAP) Details				
NTAP ICD-10-PCS	Codes⁴	Descriptions ⁴		
codes	XW033QB	Introduction of lloprost into Peripheral Vein, Percutaneous Approach, New Technology Group 11		
	XW043QB	Introduction of Iloprost into Central Vein, Percutaneous Approach, New Technology Group 11		
NTAP payment amount	The lesser4: 1. 65% of the cost of AURLUMYN, or 2. 65% of the amount by which the total covered costs of the case exceed the MS-DRG payment The maximum payment is \$28,600* per admission. *The current NTAP estimated maximum payment of \$28,600 was based on an estimated cost of \$44,000 per patient, assuming the use of 8, single-use 100 mcg per mL vials (1 per day over 8 days) at a cost of \$5500 per vial. If the total covered costs of the case do not exceed the MS-DRG payment, then no additional payment is made for the admission.			
Product J-code	Coding System	Code and Description		
	HCPCS ⁵	J1749 Injection, iloprost, 0.1 mcg		
Effective date	• October 1, 2025 ^{4,6}			
	CMS will provide add-on payments through FY 2028			

Ordering and distribution information		
Ordering information	AURLUMYN is available through specialty distribution. Please see the specialty distributor listed below.	
Distribution	ASD Healthcare 1-800-746-6273 Cardinal Health SPD 1-855-855-0708 FFF Enterprises Inc. 1-800-843-7477 McKesson Plasma and Biologics, LLC 1-877-625-2566 Please see AURLUMYN.com for up-to-date distribution information.	

IMPORTANT SAFETY INFORMATION (cont'd)

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.

CMS, Centers for Medicare & Medicaid Services; ICD-10-PCS, International Classification of Diseases, 10th Revision, Procedure Coding System; MS-DRG, Medicare Severity Diagnosis Related Group; SPD, Specialty Pharmaceutical Distribution.





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Key product and packaging information				
Dimensions and weight	Carton dimensions ⁷	Package quantity ¹	Carton weight ⁷	
	1.35 in x 1.40 in x 2.85 in	1 vial (per carton)	0.035 lb	
Storage and handling	 Unopened vials of AURLUMYN are stable until the date indicated on the package when stored at 20°C to 25°C (68°F to 77°F).¹ The unopened vial should be kept in the carton and not exposed to direct sunlight. 			
	Do not freeze. ¹			
Expiration date and shelf life	AURLUMYN has a 36-month shelf life from the date of manufacture when stored at 20°C to 25°C (68°C to 77°C). The expiration date is printed on each AURLUMYN carton.\(^18\)			
Dosage and administration	Recommended dosing regimen Administer AURLUMYN as a continuous intravenous infusion over 6 hours each day for up to a maximum of 8 consecutive days.			
	Dosage for patients with hepatic or renal impairment			
	Dosage adjustment is recommended for patients with moderate or severe hepatic impairment (Child-Pugh Class B or C) and may be necessary for patients with renal impairment with eGFR <30 mL/min. Dosage adjustment can be considered based on tolerability and should follow the guidance for these patient populations in Section 2.3 and Section 2.4 of the full AURLUMYN Prescribing Information. ¹			
	Key dilution considerations			
	AURLUMYN should only be diluted using 0.9% Sodium Chloride Injection, USP. Do not dilute or mix AURLUMYN with any other parenteral medications or solutions prior to or during administration. ¹			
Parenteral drug products should be inspected visually for particulate matter prior to administration, whenever solution and container permit. Do not use particles, discoloration, or foreign particles are observed.			culate matter and discoloration . Do not use if visibly opaque	
		MYN infusion solution. If not used temperature (20°C to 25°C [68°		
		siderations and procedures for A NURLUMYN <u>Prescribing Information</u>		

Product and medical information support		
Product replacement	For questions regarding replacement, please contact Customer Service at 1-844-293-0007.	
Product information, adverse event reporting, and product complaints	For additional information about AURLUMYN, to report adverse events, or to file a product complaint, contact SERB Medical Information (available 24 hours). 1-877-377-3784 serbmedinfo@serb.com	

eGFR, estimated glomerular filtration rate; USP, United States Pharmacopeia.





Indications and Important Safety Information

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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: 1. AURLUMYN® [package insert]. West Conshohocken, PA: BTG International, Inc. 2. SERB Pharmaceuticals expands leading emergency care portfolio with acquisition of Aurlumyn® (iloprost IV) for severe frostbite. SERB Pharmaceuticals. October 21, 2024. Accessed September 25, 2025. https://serb.com/news/serb-pharmaceuticals-expands-leading-emergency-care-portfolio-with-acquisition-of-aurlumyn-iloprost-iv-for-severe-frostbite/ 3. Data on file. Medi-Span Price Rx Pro data sheet. BTG International, Inc.; 2025. 4. Federal Register Volume 90 No. 147: rules and regulations. Centers for Medicare and Medicaid Services. August 4, 2025. Accessed September 23, 2025. https://www.govinfo.gov/content/pkg/FR-2025-08-04/pdf/2025-14681.pdf 5. HCPCS code for injection, iloprost, 0.1 mcg J1749. The American Academy of Professional Coders. Accessed September 24, 2025. https://www.aapc.com/codes/hcpcs-codes/J1749?srsltid=AfmBOoqoBqizGqXTRNLjbRUn4Ae2LdLljDjPplryJhLTeo6lhH0GNPb] 6. General schedule of rulemaking for Medicare payment systems. Centers for Medicare and Medicaid Services. September 10, 2024. Accessed September 23, 2025. https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/payment/rulemaking-schedule 7. Data on file. AURLUMYN carton dimensions and weight. BTG International, Inc.; 2024. 8. Data on file. REF-3409. BTG International, Inc.; May 2025.

Please see full Prescribing Information for AURLUMYN.

