

Highmark Medicare Advantage Medical Policy-PA/DE/NY

Medical Policy: I-175-0089
Topic (or Title): Octreotide acetate (Sandostatin, Sandostatin LAR) and Lanreotide (Somatuline Depot)
Section: Injections
Effective Date: ~~October 6, 2025~~ May 1, 2026
Issued Date: ~~October 6, 2025~~ May 1, 2026
Last Revision Date: ~~July 2025~~ February 2026

Octreotide acetate is a somatostatin analogue indicated for treatment of acromegaly, severe diarrhea/flushing episodes associated with metastatic carcinoid tumors and profuse watery diarrhea associated with vasoactive intestinal peptide (VIP) secreting tumors. Sandostatin can be given intravenously or subcutaneously, Sandostatin LAR depot formulation is given intramuscularly and Somatuline Depot is given via deep subcutaneous injection.

Policy Position

Approved Use

Drugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective when used for indications specified on the labeling. Please refer to product specific labeling for approved indications. Coverage is also dictated by National Coverage Determinations or the appropriate Local Coverage Determinations

Unlabeled Use

Octreotide acetate (Sandostatin, Sandostatin LAR), Lanreotide and Somatuline Depot may be considered medically necessary for treatment of **ANY** of the following:

- Micromedex DrugDex Compendium® Class I, Class IIa, or Class IIb indications; **or**
 - Use supported in the American Hospital Formulary Service Drug Information (AHFS-DI) ;
- or**
- Use supported in Clinical Pharmacology™ Compendium; **or**
 - Indication listed in Lexi-Drugs as “Use: off-Label” and rated as “Evidence Level A”.

Octreotide acetate (Sandostatin, Sandostatin LAR), Lanreotide and Somatuline Depot is considered not medically necessary for **ANY** of the following:

- Micromedex DrugDex Compendium® Class III indications; **or**
- Narrative text in AHFS or Clinical Pharmacology is “not supportive”; **or**
- Indication listed in Lexi-Drugs as “Use: Unsupported”; **or**
- Indication not FDA-labeled and not listed in any compendia.

Octreotide acetate (Sandostatin, Sandostatin LAR), Lanreotide and Somatuline Depot may be considered medically necessary for treatment of any of the current category 1, 2A, or 2B NCCN recommendations.

The use of octreotide acetate (Sandostatin, Sandostatin LAR), lanreotide and Somatuline Depot not meeting the criteria as indicated in this policy is considered experimental/investigational, and therefore, not medically necessary.

Procedure Codes

J1930

J1932

J2353

J2354

NOTE: In addition to the above criteria, product specific dosage and/or frequency limits may apply in accordance with the U.S. Food and Drug Administration (FDA)-approved product prescribing information, national compendia, Centers for Medicare and Medicaid Services (CMS) and other peer reviewed resources or evidence-based guidelines. Highmark may deny, in full or in part, reimbursement for utilization that does not fall within the applicable dosage and/or frequency limits.

Diagnosis Codes

Covered Diagnosis Codes for Procedure Code J2353

E16.1	E16.3	E16.4	E16.8	E16.A1	E16.A2	E16.A3
E22.0	E31.21	E31.22	E31.23	E312.0	I85.01	I85.11
K52.0	R19.7	T66.XXXA	T66.XXXD	T66.XXXS		

Removing:

C25.4	C37	C4A.0	C4A.10	C4A.111	C4A.112	C4A.121
C4A.122	C4A.20	C4A.21	C4A.22	C4A.30	C4A.31	C4A.39
C4A.4	C4A.51	C4A.52	C4A.59	C4A.60	C4A.61	C4A.62
C4A.70	C4A.71	C4A.72	C4A.8	C4A.9	C70.0	C70.1
C70.9	C74.10	C74.11	C74.12	C74.90	C74.91	C74.92
C75.5	C7A.00	C7A.011	C7A.012	C7A.019	C7A.020	C7A.021
C7A.022	C7A.023	C7A.024	C7A.025	C7A.026	C7A.029	C7A.090
C7A.091	C7A.092	C7A.093	C7A.094	C7A.095	C7A.096	C7A.098
C7A.1	C7A.8	C7A0.10	C7B.00	C7B.01	C7B.02	C7B.03
C7B.04	C7B.09	C7B.1	C7B.8	D15.0	D32.0	D32.1
D32.9	D38.4	D3A.00	D3A.010	D3A.011	D3A.012	D3A.019
D3A.020	D3A.021	D3A.022	D3A.023	D3A.024	D3A.025	D3A.026
D3A.029	D3A.090	D3A.091	D3A.092	D3A.094	D3A.095	D3A.096
D3A.098	D42.0	D42.1	D42.9	E34.00	E34.01	E34.09

Covered Diagnosis Codes for Procedure Code J2354

E16.1	E16.3	E16.4	E16.8	E16.A1	E16.A2	E16.A3
E22.0	E31.20	E31.21	E31.22	E31.23	I85.01	I85.11
K52.0	R19.7	T66.XXXA	T66.XXXD	T66.XXXS		

Removing:

C25.4	C37	C70.0	C70.1	C70.9	C74.10	C74.11
C74.12	C74.90	C74.91	C74.92	C75.5	C7A.00	C7A.010
C7A.011	C7A.012	C7A.019	C7A.020	C7A.021	C7A.022	C7A.023
C7A.024	C7A.025	C7A.026	C7A.029	C7A.090	C7A.091	C7A.092
C7A.093	C7A.094	C7A.095	C7A.096	C7A.098	C7A.8	C7B.00
C7B.01	C7B.02	C7B.03	C7B.04	C7B.09	C7B.8	D15.0
D32.0	D32.1	D32.9	D38.4	D42.0	D42.1	D42.9
E34.00	E34.01	E34.09				

Covered Diagnosis Codes for Procedure Code J1930 and J1932

E16.1	E16.3	E16.4	E16.8	E16.A1	E16.A2	E16.A3
E22.0	E31.20	E31.21	E31.22	E31.23	I85.01	I85.11
K76.6	R19.7	T82.855A	T82.855D	T82.855S		

Removing:

C25.4	C74.10	C74.11	C74.12	C74.90	C74.91	C74.92
C75.5	C7A.00	C7A.010	C7A.011	C7A.012	C7A.019	C7A.020
C7A.021	C7A.022	C7A.023	C7A.024	C7A.025	C7A.026	C7A.029
C7A.090	C7A.091	C7A.092	C7A.093	C7A.094	C7A.095	C7A.096
C7A.098	C7A.8	C7B.00	C7B.01	C7B.02	C7B.03	C7B.04
C7B.09	C7B.8	D3A.00	D3A.010	D3A.011	D3A.012	D3A.019
D3A.020	D3A.021	D3A.022	D3A.023	D3A.024	D3A.025	D3A.026
D3A.029	D3A.090	D3A.091	D3A.092	D3A.094	D3A.095	D3A.096
D3A.098	E34.00	E34.01	E34.09			

The policy position applies to all Medicare Advantage lines of business

Links

- [Link to Provider Resource Center for the Medical Policy Update](#)

09/2017 Coverage criteria established for Octreotide acetate (Sandostatin, Sandostatin LAR) and Lanreotide (Somatuline Depot)

- [Link to References](#)

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect Highmark's reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract, and subject to the applicable laws of your state.

Highmark retains the right to review and update its medical policy guidelines at its sole discretion. These guidelines are the proprietary information of Highmark. Any sale, copying or dissemination of the medical policies is prohibited; however, limited copying of medical policies is permitted for individual use.

Discrimination is Against the Law

The Claims Administrator/Insurer complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. The Claims Administrator/Insurer does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex. The Claims Administrator/ Insurer:

- *Provides free aids and services to people with disabilities to communicate effectively with us, such as:*
 - *Qualified sign language interpreters*
 - *Written information in other formats (large print, audio, accessible electronic formats, other formats)*

- *Provides free language services to people whose primary language is not English, such as:*
 - *Qualified interpreters*
 - *Information written in other languages*

If you need these services, contact the Civil Rights Coordinator.

If you believe that the Claims Administrator/Insurer has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: Civil Rights Coordinator, P.O. Box 22492, Pittsburgh, PA 15222, Phone: 1-866-286-8295, TTY: 711, Fax: 412-544-2475, email: CivilRightsCoordinator@highmarkhealth.org. You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

*U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)*

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Insurance or benefit/claims administration may be provided by Highmark, Highmark Choice Company, Highmark Coverage Advantage, Highmark Health Insurance Company, First Priority Life Insurance Company, First Priority Health, Highmark Benefits Group, Highmark Select Resources, Highmark Senior Solutions Company or Highmark Senior Health Company, all of which are independent licensees of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield plans.

DRAFT

ATTENTION: If you speak English, language assistance services, free of charge, are available to you. Call the number on the back of your ID card (TTY: 711).

ATENCIÓN: Si usted habla español, servicios de asistencia lingüística, de forma gratuita, están disponibles para usted. Llame al número en la parte posterior de su tarjeta de identificación (TTY: 711).

请注意：如果您说中文，可向您提供免费语言协助服务。

请拨打您的身份证背面的号码（TTY: 711）。

CHÚ Ý: Nếu quý vị nói tiếng Việt, chúng tôi cung cấp dịch vụ hỗ trợ ngôn ngữ miễn phí cho quý vị. Xin gọi số điện thoại ở mặt sau thẻ ID của quý vị (TTY: 711).

알림: 한국어를 사용하시는 분들을 위해 무료 통역이 제공됩니다. ID 카드 뒷면에 있는 번호로 전화하십시오 (TTY: 711).

ATENSYON: Kung nagsasalita ka ng Tagalog, may makukuha kang mga libreng serbisyong tulong sa wika. Tawagan ang numero sa likod ng iyong ID card (TTY: 711).

ВНИМАНИЕ: Если вы говорите по-русски, вы можете воспользоваться бесплатными услугами языковой поддержки. Позвоните по номеру, указанному на обороте вашей идентификационной карты (номер для текст-телефонных устройств (TTY): 711).

تنبيه: إذا كنت تتحدث اللغة العربية، فهناك خدمات المساعدة في اللغة المجانية متاحة لك. اتصل بالرقم الموجود خلف بطاقة هويتك (جهاز الاتصال لذوي صعوبات السمع والنطق: 711).

ATTENTION: Si c'est créole que vous connaissez, il y a un certain service de langues qui est gratis et disponible pour vous-même. Composez le numéro qui est au dos de votre carte d'identité. (TTY: 711).

ATTENTION: Si vous parlez français, les services d'assistance linguistique, gratuitement, sont à votre disposition. Appelez le numéro au dos de votre carte d'identité (TTY: 711).

UWAGA: Dla osób mówiących po polsku dostępna jest bezpłatna pomoc językowa. Zadzwoń pod numer podany na odwrocie karty ubezpieczenia zdrowotnego (TTY: 711).

ATENÇÃO: Se a sua língua é o português, temos atendimento gratuito para você no seu idioma. Ligue para o número no verso da sua identidade (TTY: 711).

ATTENZIONE: se parla italiano, per lei sono disponibili servizi di assistenza linguistica a titolo gratuito. Contatti il numero riportato sul retro della sua carta d'identità (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, steht Ihnen unsere fremdsprachliche Unterstützung kostenlos zur Verfügung. Rufen Sie dazu die auf der Rückseite Ihres Versicherungsausweises (TTY: 711) aufgeführte Nummer an.

注：日本語が母国語の方は言語アシスタンス・サービスを無料でご利用いただけます。IDカードの裏に明記されている番号に電話をおかけください (TTY: 711)。

توجه : اگر شما به زبان فارسی صحبت می کنید، خدمات کمک زبان، به صورت رایگان، در دسترس شماست. با شماره واقع در پشت کارت شناسایی خود (TTY: 711) تماس بگیرید.