Medical Policy

Outpatient Surgical Site of Service

MEDICAL POLICY NUMBER: 420

Effective Date: 1/1/2025	COVERAGE CRITERIA	. 2
Last Review Date: 10/2024	POLICY CROSS REFERENCES	. 3
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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

PLAN PRODUCT AND BENEFIT APPLICATION

⊠ Commercial	☐ Medicaid/OHP*	☐ Medicare**
*Medicaid/OHP Members		
Oregon: Services requested for Oregon H Oregon Administrative Rules (OARs) as th policy criteria below may be applied whe	ne primary resource for covera	age determinations. Medical

**Medicare Members

Prioritized List.

This <u>Company</u> policy may be applied to Medicare Plan members only when directed by a separate <u>Medicare</u> policy. Note that investigational services are considered "not medically necessary" for Medicare members.

COVERAGE CRITERIA

Notes:

- For definitions or scores referenced in criteria, see the <u>Policy Guidelines</u> immediately following this section.
- In addition to site of service review, codes for rhinoplasties, implantable cardiac loop recorders, spinal cord stimulation and dorsal root ganglion stimulation may also require general medical necessity review for all Plan members, using criteria found in separate medical policies. See <u>Policy Cross-References</u> for links to these policies.
- For Physician Attestation Form, please see <u>Ambulatory Surgery Center Access Physician</u>
 Attestation Form

General Site of Service Criteria

- The use of a hospital outpatient department instead of an ambulatory surgery center (ASC) or physician office for surgical services may be considered medically necessary when one or more of the following criteria are met (A.-H.):
 - There is no ASC within 25 miles that can provide the necessary care for the patient due to one of the following:
 - There is no geographically accessible ASC that has the necessary equipment for the procedure; or
 - There is no geographically accessible ASC available at which the individual's physician has privileges; or
 - An ASC's specific guideline regarding the individual's weight or health conditions prevents the use of an ASC

- The procedure requires discontinuing medications (e.g. antiarrhythmics, antiseizure medication), which necessitates preoperative or postoperative inpatient monitoring or treatment;
- Age 17 years and younger;
- The service being performed is in conjunction with an additional service that requires the use of a hospital outpatient department and they are being performed in the same operative session;
- Patient has any of the following anesthesia risk factors (1.-4.):
 - American Society of Anesthesiologists (ASA) Score is 3 or higher;
 - Personal history of complication of anesthesia;
 - Documentation of alcohol dependence or history of cocaine use;
 - Prolonged surgery (>3 hours); or
- Patient has any of the following cardiovascular risk factors (1.-7.):
 - Uncompensated chronic heart failure (NYHA class III or IV);
 - Recent history of myocardial infarction (< 3 months);
 - Poorly controlled, resistant hypertension (3 or more drugs to control blood pressure);
 - Recent history of cerebrovascular accident (<3 months);
 - Increased risk for cardiac ischemia (drug eluting stent placed < 1 year, or angioplasty <90 days);
 - Symptomatic cardiac arrhythmia despite medication;
 - Significant valvular heart disease; or
- Patient has any of the following pulmonary risk factors (1.-3.):
 - Chronic obstructive pulmonary disease (COPD) (FEV1 <50%);
 - Poorly controlled asthma (FEV1 <80% despite treatment);
 - Moderate to severe obstructive sleep apnea (OSA) (AHI ≥ 15); or
- o Patient has any of the following (1.-5.):
 - Advanced liver disease with a MELD score >8;
 - Bleeding disorder requiring replacement factor, blood products, or special infusion; product (not including DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin));
 - Anticoagulation use, or anticipated need for transfusion;
 - Pregnancy;
 - Morbid obesity (BMI ≥ 40).

Site of Service Criteria Not Met

• If general site of service criteria (criterion I.) is not met, the procedure will be considered **not medically necessary** in the hospital outpatient department setting.

Link to Evidence Summary

POLICY CROSS REFERENCES

- Inpatient Surgical Site of Service (Company)
- Rhinoplasty and Other Nasal Surgeries (Company)
- Implantable Spinal Cord and Dorsal Root Ganglion Stimulation (Company)

- Implantable Loop Recorder (Company)
- <u>Inpatient Hospital Admission and Length of Stay Reviews</u> (Reimbursement Policy)
- Ambulatory Surgery Center (ASC) Payment Structure (Reimbursement Policy)

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to determine the medical necessity of the request, the following documentation must be provided at the time of the request:

- Medical records to include documentation of all of the following:
 - History
 - o Physical examination including patient weight and co-morbidities
 - Surgical plan
 - American Society of Anesthesiologists Physical Classification (ASA-PS) score

DEFINITIONS

Body Mass Index (BMI)¹

Metric BMI Formula: BMI= weight (kg) ÷ height² (m²) Imperial BMI Formula: BMI= weight (lb) ÷ height² (in²) x 703

- Obesity is defined as a BMI of 30.0 kg/m² or higher.
- Obesity is frequently divided into categories:
 - \circ Class I: BMI of 30 kg/m² to < 35 kg/m²
 - \circ Class II: BMI of 35 kg/m² to < 40 kg/m²
 - o Class III: BMI of 40 kg/m² or higher
 - A BMI of 40-49.9 kg/m² is considered morbidly obese.
 - A BMI of 50 kg/m² or more is considered superobesity or super morbid obesity.

American Society of Anesthesiologists (ASA) Physical Status Classification System (ASA-PS)²

Current Definitions and ASA-Approved Examples

ASA PS Classification	<u>Definition</u>	Adult Examples, Including, but not Limited to:
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30 < BMI < 40), well-controlled DM/HTN, mild lung disease

ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Examples include (but not limited to): recent (< 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis
ASA V	A moribund patient who is not expected to survive without the operation	Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction

^{*}The addition of "E" denotes Emergency surgery: (An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part)

New York Heart Association (NYHA) Classification³

- 1. Class I No symptoms and no limitation in ordinary physical activity, eg, shortness of breath when walking, climbing stairs etc.
- 2. Class II Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
- 3. Class III Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (20–100 m). Comfortable only at rest.
- 4. Class IV Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.

Model for End-Stage Liver Disease (MELD)⁴

MELD calculator found here. The MELD score calculation uses:

- Serum Creatinine (mg/dL)*
- Bilirubin (mg/dL)
- INR
- Serum Sodium (mEq/L)

BACKGROUND

From the Noridian web page for Ambulatory Surgical Center (ASC):5,6

^{*}For patients who have had dialysis twice within the last week, or 24 hours of CVVHD, the creatinine value will be automatically set to 4 mg/dL.

"An ASC is defined as an entity that operates exclusively for furnishing outpatient surgical services to patients. To receive coverage of and payment for its services under this provision, a facility must be certified as meeting the requirements for an ASC and enter into a written agreement with CMS."

Several factors are considered when determining the appropriateness for the site of care including an individual's health status, facility and geographic availability, specialty requirements, and physician privileges. The American Society of Anesthesiologist (ASA) physical status classification system and/or significant comorbidities may be taken into account.

Procedures

Currently, the scope of this policy is limited to review of site of service appropriateness for the following procedures:

- Plastic procedure on nose (Rhinoplasty)
- Spinal cord stimulation
- Dorsal Root Ganglion (DRG) Stimulation
- Implantable loop recorder

Procedures other than these services may be added for site of service appropriateness review in the future.

Procedures:	Information:
Plastic procedure on nose (Rhinoplasty)	Rhinoplasty is a procedure performed on the external or internal structures of the nose, septum, or turbinate. This surgery may be performed to improve abnormal function, reconstruct congenital or acquired deformities, or to enhance appearance.
Spinal cord stimulation	Spinal cord stimulation (SCS) is a treatment designed to help suppress pain in specific areas for individuals suffering from chronic, refractory, neuropathic pain; most commonly, failed back surgery syndrome, complex regional pain syndrome type 1, and diabetic peripheral neuropathy. The SCS device works by delivering electrical currents through the spinal column in order to disrupt the transmission of pain signals. SCS consists of a generator that is implanted subcutaneously and directly connects to electrodes implanted in the epidural space. SCS implantation is conducted in two phases: the trial phase and the permanent implantation phase. During the trial phase, electrodes are implanted temporarily and connected to the generator. The generator is then programmed with stimulation parameters customized to the specific areas of pain. ⁷
Dorsal Root Ganglion (DRG) Stimulation	Dorsal root ganglion stimulation is a pain therapy indicated for individuals with complex regional pain syndrome types 1 or 2. "Rather than working through the spinal cord, this therapy is applied to the dorsal root ganglion, a group of specialized nerves near the spinal cord at the base of each branching spinal nerve." The DRG stimulator consists of electrical leads and an implanted pulse generator. The electrical leads are threaded through the epidural space and attached over the

	DRG. The pulse generator is also implanted subcutaneously. Patients can switch
	between stimulation settings using an external hand-held controller.9
Implantable loop	The implantable cardiac loop recorder (ICLR) is a very small ECG monitoring device
recorder	that is inserted under the skin, in the chest. ICLRs are commonly the size of a
	computer USB but newer models are much smaller, only around a few millimeters
	long. Placement of the device does require an outpatient surgical procedure, but
	once implanted the ICLR can provide ECG data for up to 3 years. These devices use a
	memory loop recording process where several minutes of ECG activity is recorded
	and then starts, or "loops," over. ICLRs can be patient activated through an external
	remote at symptom initiation or auto-activated when the monitor detects an
	arrhythmia. Data from the device is usually transmitted to a remote monitoring
	center for physician review. These monitors are particularly useful in patients who
	experience cardiac arrhythmia symptoms so infrequently that noninvasive
	ambulatory monitoring (e.g. Holter monitors or external cardiac rhythm monitors)
	is unlikely to capture a diagnostic ECG abnormality. 10

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CLINICAL EVIDENCE AND LITERATURE REVIEW

CLINICAL PRACTICE GUIDELINES

American Society of Anesthesiologists (ASA)

The American Society of Anesthesiologists (ASA) maintains a Physical Status Classification System with definitions and ASA-approved examples. This system is intended to be used in conjunction with other factors to aid in predicting perioperative risks. The system was originally proposed in 1942, and the current version was published in 2014 with the inclusion of examples, and was most recently updated in 2020.

EVIDENCE SUMMARY

A procedure reviewed under this policy may be considered medically necessary in the hospital outpatient department instead of an ambulatory surgical center (ASC) setting when criteria are met (see separate medical policies for general medical necessity criteria). Due to a lack of evidence and clinical practice guidelines based on evidence, the use of a hospital outpatient department instead of an ASC for surgical services is considered not medically necessary when the policy criteria are not met including when the procedure can be safely performed in a less intensive setting, an ASC where the physician has

privileges is geographically available, or the specific service requires prior authorization and the individual does not meet applicable policy criteria.

BILLING GUIDELINES AND CODING

COD	ES*	
Prior A	uthorization	Required
		Rhinoplasty
CPT	30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
	30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral
		and alar cartilages, and/or elevation of nasal tip
	30420	Rhinoplasty, primary; including major septal repair
	30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
	30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
	30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
		Spinal Cord Stimulator
CPT	0784T	Insertion or replacement of percutaneous electrode array, spinal, with
		integrated neurostimulator, including imaging guidance, when performed
	0785T	Revision or removal of neurostimulator electrode array, spinal, with integrated
		neurostimulator
	63650	Percutaneous implantation of neurostimulator electrode array, epidural
	63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
	63661	Removal of spinal neurostimulator electrode percutaneous array(s), including
		fluoroscopy, when performed
	63662	Removal of spinal neurostimulator electrode plate/paddle(s) placed via
		laminotomy or laminectomy, including fluoroscopy, when performed
	63663	Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
	63664	Revision including replacement, when performed, of spinal neurostimulator
		electrode plate/paddle(s) placed via laminotomy or laminectomy, including
		fluoroscopy, when performed
	63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver,
		requiring pocket creation and connection between electrode array and pulse
		generator or receiver
	63688	Revision or removal of implanted spinal neurostimulator pulse generator or
		receiver, with detachable connection to electrode array
		Patient-activated Event Recorder
CPT	33285	Insertion, subcutaneous cardiac rhythm monitor, including programming

*Coding Notes:

The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this
policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for
medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential
utilization audit.

- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code
 is submitted for non-covered services addressed in this policy then it will be denied as not covered. If an unlisted
 code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, prior
 authorization is recommended.
- See the non-covered and prior authorization lists on the Company <u>Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website</u> for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

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- 3. American Heart Association. Classes of Heart Failure. New York Heart Association (NYHA) Functional Classification,. https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/classes-of-heart-failure. Accessed 9/10/2024.
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- Centers for Medicare and Medicaid Services (CMS). Medicare Claims Processing Manual, Chapter 14 - Ambulatory Surgical Centers, §10.2 - Ambulatory Surgical Center Services on ASC List. https://www.cms.gov/Regulations-and-Guidance/Manuals/Downloads/clm104c14.pdf. Published 2023. Accessed 9/23/2024.
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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
1/2025	New policy.