aprevo® PERSONALIZED INTERBODY DEVICE CODING AND REIMBURSEMENT GUIDE

CMS Grants New Technology Add-on Payment (NTAP) for aprevo®

The Centers for Medicare and Medicaid Services (CMS) provides an **additional maximum payment of $40,950 for aprevo®**, when used in the inpatient hospital setting. NTAP is an additional payment made to the hospital on top of the MS-DRG payment for the hospital stay. This additional payment is provided to offset some of the costs of new drugs and devices when certain criteria are met. Add-on payments for devices are limited to the lesser of $40,950, or 65% of the amount by which the costs of the case exceeds the standard MS-DRG payment.

This add-on payment will be incremental to the MS-DRG payments listed below for qualifying Medicare inpatient cases. Commercial payer reimbursement will vary by contract.

Medicare FY 2022 Hospital MS-DRG Inpatient Reimbursement with and without aprevo® NTAP

MS-DRG	Description	FY2022 Payment	w. Maximum aprevo® NTAP
453	Combined Anterior/Posterior Spinal Fusion with MCC	$60,588.52	$101,538.52
454	Combined Anterior/Posterior Spinal Fusion with CC	$40,179.79	$81,129.79
455	Combined Anterior/Posterior Spinal Fusion without CC/MCC	$31,529.37	$72,479.37
456	Spinal fusion except cervical with spinal curvature, malignancy, infection or extensive fusions with MCC	$56,711.07	$97,661.07
457	Spinal fusion except cervical with spinal curvature, malignancy, infection or extensive fusions with CC	$42,835.98	$83,785.98
458	Spinal fusion except cervical with spinal curvature, malignancy, infection or extensive fusions without CC/MCC	$33,021.67	$73,971.67

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Primary ICD-10-CM Diagnosis Codes

Patients with spinal malalignment must have EITHER a primary OR secondary diagnosis code from the ICD-10-CM lists below.

M40.00	Postural kyphosis, site unspecified
M40.04	Postural kyphosis, thoracic region
M40.05	Postural kyphosis, thoracolumbar region
M40.10	Other secondary kyphosis, site unspecified
M40.14	Other secondary kyphosis, thoracic region
M40.15	Other secondary kyphosis, thoracolumbar region
M40.204	Unspecified kyphosis, thoracic region
M40.205	Unspecified kyphosis, thoracolumbar region
M40.209	Unspecified kyphosis, site unspecified
M40.294	Other kyphosis, thoracic region
M40.295	Other kyphosis, thoracolumbar region
M40.299	Other kyphosis, site unspecified
M40.30	Flatback syndrome, site unspecified
M40.35	Flatback syndrome, thoracolumbar region
M40.36	Flatback syndrome, lumbar region
M40.37	Flatback syndrome, lumbosacral region
M40.40	Postural lordosis, site unspecified
M40.45	Postural lordosis, thoracolumbar region
M40.46	Postural lordosis, lumbar region
M40.47	Postural lordosis, lumbosacral region
M40.50	Lordosis, unspecified, site unspecified
M40.55	Lordosis, unspecified, thoracolumbar region
M40.56	Lordosis, unspecified, lumbar region
M40.57	Lordosis, unspecified, lumbosacral region
M41.20	Other idiopathic scoliosis, site unspecified
M41.24	Other idiopathic scoliosis, thoracic region
M41.25	Other idiopathic scoliosis, thoracolumbar region
M41.26	Other idiopathic scoliosis, lumbar region
M41.27	Other idiopathic scoliosis, lumbosacral region
M41.30	Thoracogenic scoliosis, site unspecified
M41.34	Thoracogenic scoliosis, thoracic region
M41.35	Thoracogenic scoliosis, thoracolumbar region
M41.40	Neuromuscular scoliosis, site unspecified
M41.44	Neuromuscular scoliosis, thoracic region
M41.45	Neuromuscular scoliosis, thoracolumbar region
M41.46	Neuromuscular scoliosis, lumbar region
M41.47	Neuromuscular scoliosis, lumbosacral region
M41.50	Other secondary scoliosis, site unspecified
M41.54	Other secondary scoliosis, thoracic region
M41.55	Other secondary scoliosis, thoracolumbar region
M4156	Other secondary scoliosis, lumbar region
M41.57	Other secondary scoliosis, lumbosacral region
M41.80	Other forms of scoliosis, site unspecified
M41.84	Other forms of scoliosis, thoracic region
M41.85	Other forms of scoliosis, thoracolumbar region
M41.86	Other forms of scoliosis, lumbar region
M41.87	Other forms of scoliosis, lumbosacral region
M41.9	Scoliosis, unspecified
M43.8X4	Other specified deforming dorsopathies, thoracic region
M43.8X5	Other specified deforming dorsopathies, thoracolumbar region
M43.8X6	Other specified deforming dorsopathies, lumbar region
M43.8X7	Other specified deforming dorsopathies, lumbosacral region
M43.8X8	Other specified deforming dorsopathies, sacral and sacrococcygeal region
M43.8X9	Other specified deforming dorsopathies, site unspecified
M43.9	Deforming dorsopathy, unspecified
M48.50XA	Collapsed vertebra, not elsewhere classified, site unspecified, initial encounter for fracture
M48.54XA	Collapsed vertebra, not elsewhere classified, thoracic region, initial encounter for fracture
M48.55XA	Collapsed vertebra, not elsewhere classified, thoracolumbar region, initial encounter for fracture
M48.56XA	Collapsed vertebra, not elsewhere classified, lumbar region, initial encounter for fracture
M48.57XA	Collapsed vertebra, not elsewhere classified, lumbosacral region, initial encounter for fracture
M48.58XA	Collapsed vertebra, not elsewhere classified, sacral and sacrococcygeal region, initial encounter for fracture
M80.08XA	Age-related osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M80.88XA	Other osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M84.58XA	Pathological fracture in neoplastic disease, other specified site, initial encounter for fracture
M84.68XA	Pathological fracture in other disease, other site, initial encounter for fracture
M96.2	Postradiation kyphosis
M96.3	Postlaminectomy kyphosis
M96.4	Postsurgical lordosis
M96.5	Postradiation scoliosis
Q67.5	Congenital deformity of spine
Q76.3	Congenital scoliosis due to congenital bony malformation
Q76.425	Congenital lordosis, thoracolumbar region
Q76.426	Congenital lordosis, lumbar region
Q76.427	Congenital lordosis, lumbosacral region
Q76.428	Congenital lordosis, sacral and sacrococcygeal region
Q76.429	Congenital lordosis, unspecified region

Secondary ICD-10-CM Diagnosis Codes

M40.10	Other secondary kyphosis, site unspecified
M40.14	Other secondary kyphosis, thoracic region
M40.15	Other secondary kyphosis, thoracolumbar region
M41.40	Neuromuscular scoliosis, site unspecified
M41.44	Neuromuscular scoliosis, thoracic region
M41.45	Neuromuscular scoliosis, thoracolumbar region
M41.46	Neuromuscular scoliosis, lumbar region
M41.47	Neuromuscular scoliosis, lumbosacral region
M41.50	Other secondary scoliosis, site unspecified
M41.54	Other secondary scoliosis, thoracic region
M41.55	Other secondary scoliosis, thoracolumbar region
M41.56	Other secondary scoliosis, lumbar region
M41.57	Other secondary scoliosis, lumbosacral region
M43.8X9	Other specified deforming dorsopathies, site unspecified

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The use of aprevo® should be stated in the clinician's operative notes.

ICD-10-PCS Procedure Codes for Adult Spinal Surgery with aprevo®

The International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) procedure codes are used by hospitals to report procedures performed in the hospital inpatient setting only. CMS established 12 new ICD-10-PCS procedure codes to identify surgeries for adult spinal deformity in which aprevo® is used. Cases involving the use of the aprevo® Intervertebral Body Fusion Device that are eligible for new technology add-on payments (NTAP) will be identified by any of the following ICD-10-PCS procedure codes:

XRGA0R7	Fusion of thoracolumbar vertebral joint using customizable interbody fusion device, open approach, new technology group 7 **XRGA3R7** Same as above w. percutaneous approach **XRGA4R7** Same as above w. percutaneous endoscopic approach
XRGB0R7	Fusion of lumbar vertebral joint using customizable interbody fusion device, open approach, new technology group 7 **XRGB3R7** Same as above w. percutaneous approach **XRGB4R7** Same as above w. percutaneous endoscopic approach
XRGC0R7	Fusion of 2 or more lumbar vertebral joints using customizable interbody fusion device, open approach, new technology group 7 **XRGC3R7** Same as above w. percutaneous approach **XRGC4R7** Same as above w. percutaneous endoscopic approach
XRGD0R7	Fusion of lumbosacral joint using customizable interbody fusion device, open approach, new technology group 7 **XRGD3R7** Same as above w. percutaneous approach **XRGD4R7** Same as above w. percutaneous endoscopic approach

MAC Implementation File 8 - FY 2022 New Technology Add-on Payment (NTAP) - Technologies Beginning to Receive NTAP

Technology	Maximum Add-on Payment	ICD-10-CM/PCS Codes Used to Identify Cases Eligible for NTAP	Alternative Pathways Status
aprevo®	$40,950.00	XRGA0R7, XRGA3R7, XRGA4R7, XRGB0R7, XRGB3R7, XRGB4R7, XRGC0R7, XRGC3R7, XRGC4R7, XRGD0R7, XRGD3R7, or XRGD4R7	Breakthrough

HOTLINE
866-aprevo1
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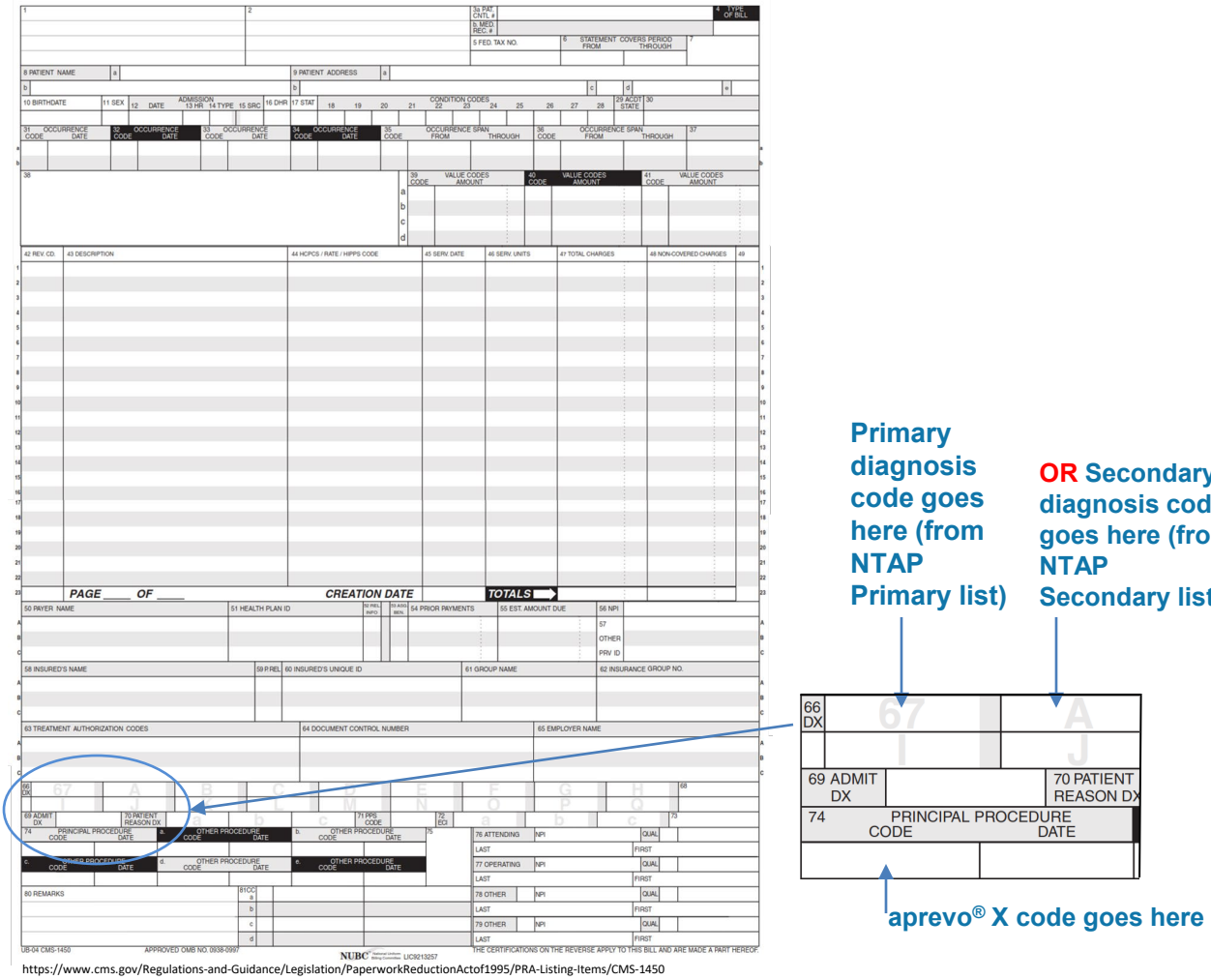
Overview of NTAP Calculation

1. Determine total covered charges for the entire hospital stay involving aprevo® surgery
2. Determine the hospital-specific operating cost-to-charge ratio (CCR)
3. Derive total covered costs of the case = Total charges * CCR
4. Determine the hospital-specific MS-DRG payment
5. Subtract the MS-DRG payment from the total covered costs of the case
6. If the difference is > $0, Medicare will make an add-on payment equal to the lesser of 65 percent of the difference or $40,950.
7. Final NTAP Payment. Determine the lesser of Step 6 or $40,950
8. Total Case Payment. NTAP plus MS-DRG

NTAP calculation for 2-level aprevo® case for MS-DRGs 453 & 454 using median hospital inpatient operating CCR of 0.254

To qualify for an NTAP, total covered case costs(based on total calculated costs) must be greater than the MS-DRG payment for that case						For qualifying cases, NTAP Amount = 65% of Excess Case Costs OR Maximum Add-On Payment – whichever is lower				Total Hospital Inpatient Payment		
	Difference Between Total Calculated Costs of Case and MS-DRG Payment					65% of the Excess Cost over MS-DRG Payment						
	Example hospital total case charges with aprevo®	x	Hospital CCR (national median)	= Hospital Total Covered Costs	- MS-DRG Payment =	Costs in Excess of MS-DRG Payment (x 0.65)	= 65% of Costs in Excess of MS-DRG	or	Maximum Add-On Payment	= New tech Add On Payment (NTAP)	MS-DRG Payment	Total Hospital Payment
	❶		❷	❸	❹	❺	❻			❼		❽
MS-DRG 453 COMBINED ANTERIOR/POSTERIOR SPINAL FUSION W MCC	$525,000	x	.254	= $133,350	– $60,588 =	$72,762 x .65	= $47,295		or $40,950	= $40,950	+ $ 60,588	= $101,538
MS-DRG 454 COMBINED ANTERIOR/POSTERIOR SPINAL FUSION W CC	$350,000	x	.254	= $88,900	– $40,179 =	$48,721 x .65	= $31,668		or $40,950	= $31,668	+ $40,179	= $71,847

Example of CMS-1450 UB-04 Form



https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-1450

Diagnosis Information

FL66: DX – Identifies the version of the ICD being reported (e.g.ICD-10)

FL67: **Principal Diagnosis Code – The full ICD-10-CM diagnosis code**, including the fourth and fifth digits, if applicable, that describes the principal diagnosis (the condition established after study to be chiefly responsible for causing the hospitalization or use of other hospital services). Present on admission indicator (POA) should be indicated in the field on the far right following the code.

FL67 A-Q: **Other Diagnosis Code – This field contains the full ICD-10-CM diagnosis codes,** including the fourth and fifth digits, if applicable, corresponding to all conditions that coexist at the time of admission, that develop subsequently or that affect the treatment received and/or the length of stay. Diagnoses that relate to an earlier episode that has no bearing on the current hospital stay should be excluded. Present on admission indicator (POA) should be indicated in the field on the far right following the code.

Procedure codes

FL74: **Principal Procedure Code/Date** - The **ICD-10-PCS for the principal procedure** performed during the period covered by the bill and the date on which the principal procedure described on the bill was performed. For inpatient and home IV therapy services, if surgery is performed during the inpatient stay from which the course of therapy is initiated**. This will be the aprevo® X code.**

Transitional Pass-Through Payment for aprevo®

Transitional Pass-Through Payment (TPT) gives beneficiaries access to the advantages of new technologies by providing adequate payment for these new devices while Medicare collects the necessary cost data, which it will use for APC assignment in the future. Carlsmed's aprevo® was granted a Transitional Pass-Through Payment as part of the quarterly update of the October 2021 Medicare Hospital Outpatient Prospective Payment System.

A Transitional Pass-Through Payment is intended to reimburse hospitals for the incremental cost of a device when the cost of the device exceeds the current device-related portion of the Ambulatory Payment Classification (APC) payment for the associated procedure.

Carlsmed's aprevo® became eligible for Transitional Pass-Through Payment on October 1, 2021. The pass-through payment amount is based on the hospital's charges for aprevo® and the individual hospital's cost-to-charge ratio.

C1831 Personalized, cage (implantable)

The HCPCS supply item code developed specifically for aprevo® is C1831, Revenue Code 278, and should be reported on services involving CPT 22630 or 22633.

CPT Code	Description
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace) other than for decompression), single interspace and segment, lumbar

Questions? Contact the Personalized aprevo® Coding Check (PaCC™) Hotline
866aprevo1 (866-277-3861) 8:30am ET – 7:00pm ET, M-F
After hours, call returned within 24 hours.
Or email to: spinecode@aprevo.com

carlsmed

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aprevo® FDA Cleared Indications for Use

The **aprevo® anterior lumbar interbody fusion and aprevo® lateral lumbar interbody fusion devices** are intended for interbody fusion in skeletally mature patients and are to be used with supplemental fixation instrumentation cleared for use in the lumbar spine. The aprevo® anterior lumbar interbody fusion and aprevo® lateral lumbar interbody fusion devices are indicated for use as an adjunct to fusion at one or more levels of the lumbar spine in patients having an ODI > 40 and diagnosed with severe symptomatic adult spinal deformity (ASD) conditions. These patients should have had six months of non-operative treatment. The devices are intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches may include anterior lumbar interbody fusion or lateral lumbar interbody fusion.

The **aprevo® transforaminal interbody device** is intended for interbody fusion in skeletally mature patients and is to be used with supplemental fixation instrumentation cleared for use in the lumbar spine. The aprevo® Personalized Interbody device is indicated for use as an adjunct to fusion at one or more levels of the lumbar spine in patients having an ODI > 40 and diagnosed with severe symptomatic adult spinal deformity (ASD) conditions. These patients should have had six months of non-operative treatment. The device is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft. These implants may be implanted via a variety of open or minimally invasive approaches.

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