Certificates of Medical Necessity

for Lumbar Total Disc Replacement by Medical Policy

Aesculap Spine

AESCULAP®
Implant Systems

Certificates of Medical Necessity Overview

This interactive document contains the Certificates of Medical Necessity specific to insurers with positive coverage of Lumbar Total Disc Replacement (LTDR) as well as a Nonspecific Certificate of Medical Necessity for all insurers not listed. The necessary Certificate of Medical Necessity can be sent directly to the commercial payer once all requirements are captured in the patient's chart. Please be aware that the Certificate of Medical Necessity may also be duplicated into your Electronic Medical Record (EMR) system from this document for ease of use.

For Commercial Insurers with Positive Coverage for LTDR:

If the patient's insurer has positive coverage of LTDR, the surgeon should use the Certificate of Medical Necessity specific to that patient's insurance during the appointment to ensure all requirements are captured in the patient's chart prior to the office's submission for prior authorization. If an insurer-specific Certificate of Medical Necessity is not available in this document, please use the Nonspecific Certificate of Medical Necessity.

- **Written Prior Authorization**
  It is critical that, after the appointment for a patient with positive coverage for LTDR, the office seek written prior authorization. If all conservative care records and other records as required by the Medical Policy as noted in the Certificate of Medical Necessity are not provided, even a covering payer will deny the procedure. Exhaustive records submitted upon initial prior authorization are critical to the success of the patient's access to this procedure.

- **Denial of Written Prior Authorization**
  If the office receives a denial for a written prior authorization for a payer covering LTDR and the patient meets the Certificate of Medical Necessity requirements, **call the Patient Assistance Line (PAL)**, (contact information found below).

For Commercial Insurers without Positive Coverage for LTDR:

If the patient's insurer does not cover LTDR, the surgeon should still complete the Certificate of Medical Necessity, regardless of payer coverage status, as a back-up to surgeon charting. The Patient Assistance Line can assist in advocating for patients that are candidates for LTDR without positive coverage. Please find the PAL contact information below.

The activL Artificial Disc Patient Assistance Line (PAL)
Telephone: 844-245-1140
Fax: 844-285-1330
Cynthia@patientassistanceline.com

Disclaimer: This information is provided for informational purposes only. Healthcare providers are responsible for all decisions related to reimbursement. Providers are advised to contact payers to confirm benefits and coverage for each individual patient. The content above is subject to change without notice, as may be determined by the payer. Aesculap Implant Systems, LLC makes no representation or warranty regarding this information, its completeness or accuracy, and bears no responsibility for the results or consequences of the use of this information. It is intended to be a general overview of medical necessity criteria for this health plan. The criteria and contraindications checklist above may not be the same as the Indications/Contraindications approved by FDA. The above information represents acceptance criteria of the Healthcare Provider.

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Interactive Table of Contents by Payer

(Please click on the below commercial payer for a Certificate of Medical Necessity specific to their medical policy.)

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

AIM Specialty Health	
Policy Name: Lumbar Disc Arthroplasty	
Effective Date: May 18, 2019	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

- ☐ Age 18 to 60 years old; **and**
- ☐ Primary complaint of axial pain to be of discogenic origin; **and**
- ☐ Symptoms for at least one year, which have not responded to a multifaceted program of conservative treatment over that period of time. Conservative management to include a combination of strategies; **and**
- ☐ Presence of single level, advanced disc disease at L4-5 or L5-S1, as documented by magnetic resonance imaging (MRI) and plain radiographs demonstrating moderate to severe degeneration of the disc with Modic changes (peridiscal bone signal above and below the disc space in question). All imaging must be performed and read by an independent radiologist. Imaging studies should correlate with the clinical findings; **and**
- ☐ Absence of disease at all other lumbar levels as documented by normal radiographs and MRI showing no abnormalities or mild degenerative changes; **and**
- ☐ Significant pain and functional impairment refer to pain that is at least 3 out of 10 in intensity and is associated with inability to perform at least (2) ADLs and/or IADLs
- ☐ Adherence to tobacco-cessation program resulting in abstinence from tobacco for at least 6 weeks prior to spinal surgery is recommended

Does not have any of the following contraindications:

- ☐ Significant facet arthropathy at the operated level
- ☐ Disease above L4-L5
- ☐ Bony lumbar spinal stenosis
- ☐ Pars defect
- ☐ Clinically compromised vertebral bodies at affected level due to current or past trauma
- ☐ Lytic spondylolisthesis or degenerative spondylolisthesis of grade greater than 1
- ☐ Allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene, titanium)
- ☐ Presence of infection or tumor
- ☐ Osteopenia or osteoporosis (defined as dual-energy x-ray absorptiometry (DEXA) bone

The procedure is not comprised of any of the following deemed not medically necessary per your medical policy:

- ☐ Disc replacement at more than one spinal level
- ☐ Arthroplasty below, or in combination with, spinal fusion or other stabilizing-type procedure
- ☐ Isolated radicular compression syndromes, especially due to disc herniation
- ☐ Hybrid lumbar TDA/Lumbar Fusion (lumbar total disc arthroplasty at one level at the same time as lumbar fusion at a different level)
- ☐ Arthroplasty using devices other than those which are FDA approved, or use of an FDA-approved device in a manner which does not meet FDA requirements

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

☐ Other:
☐ Notes:
Device Requirements:
☐ Must be FDA approved and used per FDA labeling
☐ Single-level use only
Enclosures
Enclosed is the following documentation as required by your policy:
☐ Medical records with evidence of at least one year of failed conservative treatment
☐ Radiographs with evidence of degenerative disc disease with one confirmed symptomatic level
Certification and Signature
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.

Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

BCBS of Arkansas	
Policy Name: Artificial Intervertebral Disc, Lumbar Spine	
Policy Number: 2004002	
Effective Date: March 2015	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

☐ 18 to 60 years old; **and**
☐ Advanced single-level disease noted on an MRI and plain radiographs of the lumbar spine at L4-L5 or L5-S1, characterized by moderate to severe degeneration of the disc; **and**
☐ Primary complaint of axial pain with a possible secondary complaint of lower extremity pain; **and**
☐ Presence of symptoms for at least one year that are not responsive to conservative treatment which should include a physical therapy/rehabilitation program; **and**
☐ Absence of active significant psychiatric disorders, such as major depression requiring pharmaceutical treatment; **and**
☐ Absence of significant facet arthropathy at the operative level

Does not have any of the following contraindications:

☐ Lumbar artificial intervertebral disc replacement in all other situations does not meet member benefit certificate primary coverage criteria thus the procedure is considered investigational.

☐ Other:
☐ Notes:
Device Requirements:
☐ Must be FDA approved and used per FDA labeling
☐ Single-level use only

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Enclosures	
Enclosed is the following documentation as required by your policy:	
☐ Medical records with evidence of at least one year of failed conservative treatment	
☐ Radiographs with evidence of degenerative disc disease with one confirmed symptomatic level	
☐ Behavioral health screening results	
Certification and Signature	
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.	
Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

BCBS of Louisiana	
Policy Name: Artificial Intervertebral Disc: Lumbar Spine	
Policy Number: #00145	
Effective Date: September 4, 2018	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

☐ Age 18 to 60 years old; **and**
☐ Primary complaint of axial pain to be of discogenic origin; **and**
☐ Symptoms for at least one year, which have not responded to a multifaceted program of conservative treatment over that period of time. Conservative management to include a combination of strategies; **and**
☐ Presence of single level, advanced disc disease at L4-L5 or L5-S1, as documented by magnetic resonance imaging (MRI) and plain radiographs demonstrating moderate to severe degeneration of the disc with Modic changes (peridiscal bone signal above and below the disc space in question). All imaging must be performed and read by an independent radiologist. Imaging studies should correlate with the clinical findings; **and**
☐ Absence of disease at all other lumbar levels as documented by normal radiographs and MRI showing no abnormalities or mild degenerative changes; **and**
☐ Documented significant pain and impairment: Pain that is at least 3 out of 10 in intensity and is associated with inability to perform at least two (2) ADL's
☐ Absence of contraindications listed below

Does not have any of the following contraindications:

☐ Significant facet arthropathy at the operated level
☐ Disease above L4-L5
☐ Bony lumbar spinal stenosis
☐ Pars defect
☐ Clinically compromised vertebral bodies at affected level due to current or past trauma
☐ Lytic spondylolisthesis or degenerative spondylolisthesis of grade greater than 1
☐ Allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene, titanium)
☐ Presence of infection or tumor
☐ Osteopenia or osteoporosis (defined as dual-energy x-ray absorptiometry [DEXA] bone density measured T-score less than -1.0)

The procedure is not comprised of any of the following deemed not medically necessary per your medical policy:

☐ Disc replacement at more than one spinal level; OR
☐ Arthroplasty below, or in combination with, spinal fusion or other stabilizing-type procedure
☐ Isolated radicular compression syndromes, especially due to disc herniation
☐ Hybrid lumbar total disc arthroplasty (TDA)/Lumbar Fusion (lumbar TDA at one level at the same time as lumbar fusion at a different level)
☐ Arthroplasty using devices other than those which are U.S. Food and Drug Administration (FDA) approved, or use of an FDA-approved device in a manner which does not meet FDA requirements.

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

☐ Other:
☐ Notes:
Device Requirements:
☐ Must be FDA approved and used per FDA labeling
☐ Single-level use only
Enclosures
Enclosed is the following documentation as required by your policy:
☐ Medical records with evidence of at least one year of failed conservative treatment and DEXA scan results
☐ Radiographs with evidence of degenerative disc disease with one confirmed symptomatic level
Certification and Signature
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.

Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

BCBS of North Dakota	
Policy Name: Artificial Intervertebral Disc Replacement	
Policy Number: #00145	
Effective Date: July 1, 2018	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

- ☐ One-level degenerative disc disease (DDD) from L4-S1 as shown on CT or MRI; and
- ☐ Failure of 3 months of conservative therapy including BOTH of the following:
  - ☐ A trial of non-steroidal anti-inflammatories (NSAIDs); and
  - ☐ A documented trial of up to six-weeks of physical therapy; and
- ☐ The individual is between 18-65 years old; and
- ☐ Symptoms are localizable to one-level in the L4-S1 area; and
- ☐ Absence of moderate or severe facet joint arthropathy confirmed by CT or MRI.
- ☐ Lumbar artificial intervertebral disc replacement is considered experimental/investigational and therefore non-covered when ALL of the above criteria are not met.

☐ Other:

☐ Notes:

Enclosures

Enclosed is the following documentation as required by your policy:

- ☐ Medical records with evidence of 3+ months of failed conservative treatment
- ☐ Radiographs with evidence of degenerative disc disease with one confirmed symptomatic level

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Certification and Signature	
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.	
Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Blue Shield of California

Policy Name: Lumbar total disc arthroplasty (artificial disc replacement)

Policy Number: BSC_NIA_CG_304

Effective Date: July 1, 2019

Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	

Primary ICD-10-CM Diagnosis Code *(Please Check One)*

- ☐ M51.36 Other intervertebral degeneration, lumbar
- ☐ M51.37 Other intervertebral degeneration, lumbosacral
- ☐ M51.26 Other intervertebral disc displacement, lumbar
- ☐ M51.27 Other intervertebral disc displacement, lumbosacral
- ☐ Other

Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*

- ☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open
- ☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open

Primary CPT® Procedure Code

- ☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

- ☐ Between ages of 18 and 60
- ☐ Degenerative disc disease or significant discogenic back pain with disc degeneration confirmed by documented patient history, physical exam, and radiographic studies
- ☐ No more than Grade 1 (low level) spondylolisthesis based on x-ray at operative level
- ☐ DDD is limited to the single spinal level at which the lumbar TDA is planned
- ☐ No significant facet arthropathy at operative level
- ☐ At least six months of non-operative treatment noted in medical records, including physical therapy/rehabilitation program with cognitive behavioral components, pain management injections and active exercise program

Does not have any of the following contraindications:

- ☐ Disease above L4-L5 (for activL® Artificial Disc)
- ☐ Active systemic or local infection
- ☐ Osteoporosis or osteopenia or vertebral bodies compromised by disease or prior trauma
- ☐ Allergy or sensitivity to implant materials
- ☐ Isolated lumbar radiculopathy (especially due to herniated disc) or chronic radiculopathy (unremitting especially leg symptoms lasting over 1 year)
- ☐ Spinal stenosis or scoliosis
- ☐ Spondylolisthesis greater than Grade 1
- ☐ Disc degeneration requiring treatment of more than one level
- ☐ Severe facet arthrosis or joint degeneration
- ☐ Presence of free disc fragment
- ☐ Myelopathy
- ☐ Morbid obesity
- ☐ Psychosocial risk factors

☐ Other:

☐ Notes:

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Device Requirements:	
☐ Must be FDA approved and used per FDA labeling	
☐ Single-level use only	
Enclosures	
Enclosed is the following documentation as required by your policy:	
☐ Medical records with evidence of 6+ months of failed conservative treatment	
☐ Radiographs with evidence of degenerative disc disease with one confirmed symptomatic level	
Certification and Signature	
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.	
Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

CareFirst	
Policy Name: Vertebral Disc Replacement: Lumbar Disc Prostheses	
Policy Number: 7.01.088	
Effective Date: April 16, 2018	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

☐ Skeletally mature
☐ DDD at only one (1) level in the lumbar spine from L4-S1
☐ Have had no relief from pain after at least 6 months of non-surgical treatment
☐ No more than 3 mm spondylolisthesis at the involved level

Does not have any of the following contraindications:

☐ Active systemic infection or infection localized to the site of implantation;
☐ Osteopenia or osteoporosis defined as DEXA bone density measured T-score < -1.0;
☐ Bony lumbar spinal stenosis;
☐ Allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene, titanium);
☐ Isolated radicular compression syndromes, especially due to disc herniation;
☐ Pars defect;
☐ Involved vertebral endplate that is dimensionally smaller than 34.5 mm in the medial-lateral and / or 27 mm in the anterior-posterior directions;
☐ Clinically compromised vertebral bodies at the affected level due to current or past trauma;
☐ Lytic spondylolisthesis or degenerative spondylolisthesis of grade > 1;
☐ Prior spinal fusion;
☐ Moderate to severe degenerative facet joint disease

The procedure is not comprised of any of the following deemed not medically necessary per your medical policy:

☐ Vertebral Disc Replacement at more than one level
☐ Patients who do not meet the above criteria.

☐ Other:
☐ Notes:

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Device Requirements:	
☐ Must be FDA approved and used per FDA labeling	
☐ Single-level use only	
Certification and Signature	
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.	
Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

CIGNA	
Policy Name: Intervertebral Disc (IVD) Prostheses	
Policy Number: 0104	
Effective Date: 10/15/2019	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

- ☐ Chronic, unremitting, discogenic low back pain and disability secondary to single-level DDD
- ☐ The implant will be inserted at an FDA approved lumbar sacral level specific to the implant being used
- ☐ Unremitting low back pain and significant functional impairment is refractory to at least six consecutive months of structured, physician supervised conservative medical management which includes ALL of the following components:
  - ☐ Exercise, including core stabilization exercises;
  - ☐ Nonsteroidal and/or steroidal medication (unless contraindicated);
  - ☐ Physical therapy, including passive and active treatment modalities;
  - ☐ Activity/lifestyle modification

The procedure is not comprised of any of the following deemed not medically necessary per your medical policy:

- ☐ Hybrid
- ☐ Simultaneous multilevel implantation is planned
- ☐ The individual has osteopenia or osteoporosis (T-score <-1.0)
- ☐ The individual has a history of prior lumbar fusion
- ☐ The implant will be inserted outside of the recommended lumbar/sacral level for the specific implant being used
- ☐ There is evidence on imaging studies of ANY of the following: degenerative spondylolisthesis of Grade 2 or greater; infection; multilevel DDD: Nerve root compression or spinal stenosis; pars interarticularis defect with either spondylolysis or isthmic spondylolisthesis; scoliosis; severe facet joint arthrosis; spinal fracture; tumor.

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

☐ Other:
☐ Notes:
Device Requirements:
☐ Must be FDA approved and used per FDA labeling ☐ Single-level use only
Enclosures
Enclosed is the following documentation as required by your policy:
☐ Medical records with evidence of 6+ months of failed conservative treatment
☐ Radiographs with evidence of degenerative disc disease with one confirmed symptomatic level
Certification and Signature
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.

Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Emblem Health	
Policy Name: Artificial Intervertebral Disc Policy	
Policy Number: MG.MM.SU.46e	
Effective Date: October 12, 2018	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

☐ Skeletally mature
☐ Disease confirmed by radiographic imaging (e.g. CT or MRI followed by a discogram)
☐ Pain confined to operative level (by discogram)
☐ No nerve root compression or narrowing of lateral recesses Grade/millimeter measurement of spondylolisthesis commensurate with the FDA- indication specific to the disc (as variance exists between the devices)
☐ Pain score greater than or equal to 40 on Visual Analog Scale (VAS)
☐ Disability score greater than or equal to 30 on the Oswestry Low Back Pain Disability Questionnaire or Neck Disability Index
☐ At least six months of consistent, conservative treatment as noted in physician office progress notes, which demonstrate at least two have been tried: physical therapy, chiropractic care, ice/heat therapy, pharmacotherapy (e.g. oral/injectable analgesia such as NSAIDS, muscle relaxants, epidural/facet injections)

The procedure is not comprised of any of the following deemed not medically necessary per your medical policy:

☐ Off label-use
☐ Insertion despite presence of contraindications identified within specific product labeling
☐ Previous spinal fusion/other spinal surgery at affected level
☐ Current or previous fracture at affected level.

☐ Other:

☐ Notes:

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Device Requirements:	
☐ Must be FDA approved and used per FDA labeling	
☐ Single-level use only	
Enclosures	
Enclosed is the following documentation as required by your policy:	
☐ Medical records with evidence of 6+ months of failed conservative treatment	
☐ Radiographs with evidence of degenerative disc disease with one confirmed symptomatic level	
Certification and Signature	
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.	
Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

eviCore	
Policy Name: Clinical Guidelines Spine Surgery: Lumbar Total Disc Arthroplasty	
Effective Date: August 1, 2019	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

- ☐ An FDA approved implant is used in accordance with FDA requirements
- ☐ Presence of chronic, unremitting, discogenic lower back pain and associated disability secondary to single-level degenerative disc disease (DDD) for at least one year.
- ☐ Age 18 to 60 years old
- ☐ Significant level of pain on a daily basis defined as EITHER of the following:
  - ☐ Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as ≥ 7
  - ☐ Severe, disabling, crippling, or incapacitating pain
- ☐ Clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing or essential job functions)
- ☐ Absence of unmanaged significant behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- ☐ Structured physician-supervised, multi-modal, nonoperative management of medical care with licensed healthcare professionals which includes ALL of the following:
  - ☐ Regularly scheduled appointments
  - ☐ Follow-up evaluation
  - ☐ Less than clinically meaningful improvement with BOTH of the following for at least 6 consecutive months unless contraindicated:
    - ☐ Prescription strength analgesics, steroids, and/or NSAIDs
    - ☐ Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician
- ☐ Moderate to severe single-level disc degeneration at L4-L5, or L5-S1 has been confirmed or recent (with 6 months) plain radiographs and advanced diagnostic imaging studies (i.e., CT, MRI)
- ☐ Absence of significant facet arthropathy at the operative level

Lumbar artificial total disc arthroplasty is considered not medically necessary for ANY of the following:

- ☐ The revision of a failed lumber total disc arthroplasty
- ☐ The planned procedure includes the combined use of a prosthesis and spinal fusion (hybrid)
- ☐ Lumbar partial disc prosthetics
- ☐ Simultaneous multilevel implantation
- ☐ The implant will be inserted outside of the spinal motion segments approved by the FDA
- ☐ The individual has osteopenia or osteoporosis (T-score <-1.0)

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

- ☐ Above or below or in combination with a spinal fusion or other stabilizing type surgical procedure
- ☐ A lumbar disc prosthesis not approved by the FDA or for an FDA approved indication
- ☐ Degenerative disc disease above L4-L5
- ☐ Presence of unmanaged significant behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- ☐ Age less than 18 or greater than 60
- ☐ As an adjunct to the treatment of primary central or far-lateral disc herniation
- ☐ There is evidence on imaging studies or ANY of the following:
  - ☐ Lytic or degenerative spondylolisthesis of Grade 2 or greater.
  - ☐ Lumbar bony spinal stenosis or Lumbar nerve root compression
  - ☐ Pars interarticularis defect with either spondylolysis or isthmic spondylolisthesis
  - ☐ Scoliosis
  - ☐ Spine fracture
  - ☐ Active systemic infection, presence of tumor or active infection at the site or implantation.
  - ☐ Multi-level degenerative disc disease (2 or more levels) on a preoperative MRI and plain radiographs
  - ☐ Significant facet arthropathy at the operated level
  - ☐ Presence of tumor or active infection at the site of implantation
  - ☐ Lumbar nerve root compression or bony spinal stenosis
- ☐ Allergy or sensitivity to implant materials
- ☐ Isolated radicular compression syndromes especially due to lumbar disc herniation
- ☐ Involved vertebral endplate that is dimensionally smaller that the approximate dimensions of the implant in anterior/posterior width
- ☐ Clinically compromised vertebral bodies at the affected level due to current or past trauma

☐ Other:
☐ Notes:

Enclosures

Enclosed is the following documentation as required by your policy:

- ☐ Medical records with evidence of 6+ months of failed conservative treatment
- ☐ Radiographs with evidence of degenerative disc disease with one confirmed symptomatic level
- ☐ Behavioral health screening

Certification and Signature

I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.

Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Excellus BCBS (Includes Univera Healthcare)	
Policy Name: Artificial Lumbar Intervertebral Disc	
Policy Number: 7.01.63	
Effective Date: June 18, 2019	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

- ☐ Use of an FDA Approved Implant
- ☐ Presence of chronic, unremitting, discogenic lower back pain and associated disability secondary to single-level degenerative disc disease (DDD) in a skeletally mature individual
- ☐ Age 18-60 years old;
- ☐ Significant level of pain on a daily basis defined as either of the following:
  1. Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as greater than or equal to 7;
  2. Severe, disabling, crippling, or incapacitating pain;
- ☐ Clinically significant functional impairment such as the inability to perform household chores, prolonged standing or essential job functions); and
- ☐ Absence of unmanaged significant behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse);
- ☐ Structured physician-supervised, multi-modal, nonoperative management of medical care with licensed healthcare professionals which includes ALL of the following:
  - ☐ Regularly scheduled appointments;
  - ☐ Follow-up evaluation;
  - ☐ Less than clinically meaningful improvement with BOTH of the following for at least 6 consecutive months unless contraindicated:
    - ☐ Prescription strength analgesics, steroids, and/or NSAIDs; and
    - ☐ Provider directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician.
- ☐ Moderate to severe single-level disc degeneration at L4-L5 or L5-S1 has been confirmed on recent (within 6 months) plain X-rays and advanced diagnostic imaging studies (i.e., CT, MRI);
- ☐ Absence of significant facet arthropathy at the operative level.
- ☐ Documentation of Nicotine Free Status:
  - ☐ Patient is a non-tobacco user, or
  - ☐ Patient must have abstained from tobacco use for at least 6 weeks prior to the planned spinal fusion surgery as evidenced by lab results (cotinine level) documenting nicotine-free status (NOTE: in order to complete the prior authorization process for spinal fusion surgery, planning should allow for enough time to submit lab results performed after the 6-week tobacco abstinence period.

Does not have any of the following contraindications:

- ☐ The revision of a failed lumber total disc arthroplasty
- ☐ The planned procedure includes the combined use of a prosthesis and spinal fusion (hybrid)
- ☐ Lumbar partial disc prosthetics
- ☐ Simultaneous multilevel implantation

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

- ☐ The implant will be inserted outside of the spinal motion segments approved by the FDA
- ☐ The individual has osteopenia or osteoporosis (T-score <-1.0)
- ☐ Above or below or in combination with a spinal fusion or other stabilizing type surgical procedure
- ☐ A lumbar disc prosthesis not approved by the FDA or for an FDA approved indication
- ☐ Degenerative disc disease above L4-L5
- ☐ Presence of unmanaged significant behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- ☐ Age less than 18 or greater than 60
- ☐ As an adjunct to the treatment of primary central or far-lateral disc herniation

☐ There is evidence on imaging studies or ANY of the following:

- ☐ Lytic or degenerative spondylolisthesis of Grade 2 or greater.
- ☐ Lumbar bony spinal stenosis or Lumbar nerve root compression
- ☐ Pars interarticularis defect with either spondylolysis or isthmic spondylolisthesis
- ☐ Scoliosis
- ☐ Spine fracture
- ☐ Active systemic infection, presence of tumor or active infection at the site or implantation.
- ☐ Multi-level degenerative disc disease (2 or more levels) on a preoperative MRI and plain radiographs
- ☐ Significant facet arthropathy at the operated level

- ☐ Allergy or sensitivity to implant materials
- ☐ Isolated radicular compression syndromes especially due to lumbar disc herniation
- ☐ Involved vertebral endplate that is dimensionally smaller that the approximate dimensions of the implant in anterior/posterior width
- ☐ Clinically compromised vertebral bodies at the affected level due to current or past trauma

☐ Other:
☐ Notes:
Device Requirements:
☐ Must be FDA approved and used per FDA labeling
☐ Single-level use only
Enclosures
Enclosed is the following documentation as required by your policy:
☐ Medical records with evidence of 6+ months of failed conservative treatment
☐ Documentation of Nicotine Free Status
☐ Radiographs with evidence of degenerative disc disease with one confirmed symptomatic level
☐ Behavioral health screening results
Certification and Signature
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.

Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Geisinger Health Plan

Policy Name: Artificial Intervertebral Disc

Policy Number: MP 147

Effective Date: January 1, 2017

Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	

Primary ICD-10-CM Diagnosis Code *(Please Check One)*

- ☐ M51.36 Other intervertebral degeneration, lumbar
- ☐ M51.37 Other intervertebral degeneration, lumbosacral
- ☐ M51.26 Other intervertebral disc displacement, lumbar
- ☐ M51.27 Other intervertebral disc displacement, lumbosacral
- ☐ Other

Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*

- ☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open
- ☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open

Primary CPT® Procedure Code

- ☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

- ☐ Skeletally mature
- ☐ Single level DDD from L3-S1
- ☐ No relief from low back pain after a minimum of 6 months of failed conservative therapy (e.g. physical therapy, bracing, injections)
- ☐ **Does not have any of the following complicating conditions such as:**
  - ☐ Multi-level disease
  - ☐ Non-contained disc
  - ☐ Previous spinal fusion
- ☐ Osteoporosis
- ☐ Mid-sagittal stenosis less than 8 mm
- ☐ Positive straight leg raise radiculopathy
- ☐ Other surgery at affected level
- ☐ Significant facet arthritis
- ☐ Spinal tumor
- ☐ Morbid obesity
- ☐ Metal allergy
- ☐ Scoliosis
- ☐ More than 3 mm spondylolisthesis at the involved level

☐ Other:

☐ Notes:

Device Requirements:

- ☐ Must be FDA approved and used per FDA labeling
- ☐ Single-level use only

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Enclosures	
Enclosed is the following documentation as required by your policy:	
☐ Medical records with evidence of 6+ months of failed conservative treatment	
Certification and Signature	
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.	
Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

HCSC (BCBS TX, IL, OK, NM & MT)	
Policy Name and Number: Intervertebral Disc Prostheses	
Policy Number: 712.028	
Effective Date: November 15, 2017	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

- ☐ Skeletally mature
- ☐ DDD at only one (1) level in the lumbar spine from L3-S1, confirmed by radiographic studies (CT, MRI, x-rays, etc)
- ☐ Radicular back/leg pain that has failed a minimum of six (6) months of conservative treatment
- ☐ No more than Grade 1 (0-25%) spondylolisthesis at the involved level
- ☐ Disc will be used for single-level reconstruction following lumbar discectomy within the L3-S1 region
- ☐ Minimum Oswestry Disability Index (ODI) score equal to or > 40
- ☐ **The procedure is not comprised of any of the following deemed not medically necessary per your medical policy:**
  - ☐ For all other indications, including but not limited to, multilevel use whether done simultaneously or at different times

☐ Other:

☐ Notes:

Device Requirements:

- ☐ Must be FDA approved and used per FDA labeling
- ☐ Single-level use only

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Enclosures	
Enclosed is the following documentation as required by your policy:	
☐ Medical records with evidence of 6+ months of failed conservative treatment	
☐ Radiographs with evidence of degenerative disc disease with one confirmed symptomatic level	
Certification and Signature	
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.	
Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

HealthPartners	
Policy Name: Artificial intervertebral disc replacement – Lumbar	
Effective Date: April 1, 2017	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

Surgical implantation of an FDA-approved lumbar artificial intervertebral disc in a skeletally mature member is eligible for coverage when ALL of the following criteria are met:

- ☐ Documentation indicates chronic, unremitting discogenic low back pain and functional impairment due to single-level degenerative disc disease (DDD)
- ☐ Single-level disc degeneration has been confirmed on complex imaging studies (i.e. computerized tomography [CT] scan, magnetic resonance imaging [MRI])
- ☐ Imaging studies confirm either 3 mm or less of spondylolisthesis at the involved level or Grade 1 spondylolisthesis
- ☐ The implant will be inserted at an FDA-approved lumbar/sacral level specific to the implant being used
- ☐ Documentation indicates that the member has failed (failed is defined as unremitting low back pain and significant functional impairment refractory to conservative treatments) ≥ 6 months of structured, physician supervised conservative medical treatment which includes ALL of the following components:
  - ☐ Exercise, including core stabilization exercises
  - ☐ Non-steroidal and/or steroidal medication (unless contraindicated)
  - ☐ Physical therapy
- ☐ **The procedure is not comprised of any of the following deemed not medically necessary per your medical policy:**
  - ☐ The planned procedure includes the combined use of an artificial disc prosthesis and spinal fusion (i.e., hybrid surgery)
  - ☐ The planned procedure includes simultaneous multilevel implantation
  - ☐ The member has osteopenia or osteoporosis (T-score < -1.0)
  - ☐ The member has a history of previous fusion surgery at any lumbar vertebral level
- ☐ **There is evidence on imaging studies of ANY of the following:**
  - ☐ Degenerative spondylolisthesis of Grade 2 or greater at the involved level
  - ☐ Infection
  - ☐ Multilevel degenerative disc disease
  - ☐ Nerve root compression or spinal stenosis
  - ☐ Pars interarticularis defect with either spondylolysis or isthmic spondylolisthesis
  - ☐ Scoliosis
  - ☐ Severe facet joint arthrosis
  - ☐ Spinal fracture
  - ☐ Tumor
- ☐ The requested device is a non FDA-approved lumbar artificial intervertebral disc.

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

☐ Other:
☐ Notes:
Device Requirements:
☐ Must be FDA approved and used per FDA labeling
☐ Single-level use only
Enclosures
Enclosed is the following documentation as required by your policy:
☐ Medical records with evidence of 6+ months of failed conservative treatment
☐ Radiographs with evidence of degenerative disc disease with one confirmed symptomatic level
Certification and Signature
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.

Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Horizon BCBSNJ	
Policy Name: Artificial Intervertebral Disc: Lumbar Spine	
Effective Date: February 24, 2017	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

- ☐ Are skeletally mature;
- ☐ Have degenerative disc disease (DDD) at one level in the lumbar spine at L4-L5 or L5-S1
- ☐ Have degenerative disc disease (DDD) confirmed by member history and radiographic studies (i.e., MR imaging and provocative discography);
- ☐ Have no more than Grade I spondylolisthesis
- ☐ Have had no relief from pain after at least six months of conservative/non-operative treatment (e.g., physical therapy, facet joint injections, epidural steroids, ultrasound, manipulation, anti-inflammatory medications, analgesic medications, muscle relaxants, lumbosacral stabilization therapy)

Does not have any of the following contraindications:

- ☐ Active systemic infection or infection localized to the site of implantation,
- ☐ Osteoporosis,
- ☐ Osteopenia,
- ☐ Bony lumbar stenosis,
- ☐ Allergy or sensitivity to implant materials (e.g., cobalt, chromium, titanium, polyethylene)
- ☐ Isolated radicular compression syndromes, especially to disc herniation, or pars defect
- ☐ Involved vertebral endplate that is dimensionally smaller than 31 mm in the medial-lateral and/or 26 mm in the anterior/posterior directions
- ☐ Clinically compromised vertebral bodies at the affected level due to current or past trauma

☐ **The procedure is not comprised of any of the following deemed not medically necessary per your medical policy:**

- ☐ Use at more than one level
- ☐ Use at a spinal level(s) other than L4-L5 or L5-S1
- ☐ Use in members with prior thoracic or lumbar spinal fusion

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

☐ Other:
☐ Notes:
Device Requirements:
☐ Must be FDA approved and used per FDA labeling
☐ Single-level use only
Enclosures
Enclosed is the following documentation as required by your policy:
☐ Medical records with evidence of 6+ months of failed conservative treatment
☐ Radiographs with evidence of degenerative disc disease with one confirmed symptomatic level
Certification and Signature
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.

Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Humana	
Policy Name: Artificial Intervertebral Disc Replacement	
Policy Number: HCS-0442-014	
Effective Date: February 26, 2019	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

- ☐ DDD at ONE level, L4-5 or L5-S1, confirmed by a complex imaging study (e.g. CT, MRI, positive concordant discography)
- ☐ Failure of at least six months of conservative treatment (e.g. medications, physical therapy)
- ☐ Unrelenting low back pain and significant functional impairment (Significant functional impairment is defined as direct and measurable reduction in performance of an organ or body part)
- ☐ FDA approved lumbar/sacral level to be utilized in accordance with FDA labeling and implanted with an anterior retroperitoneal approach
- ☐ No more than Grade 1 spondylolisthesis at the involved level (Grade 1 is 25% or less of vertebral body slipping forward)
- ☐ Documentation of Skeletal Maturity

Does not have any of the following contraindications:

- ☐ Abdominal pathology precluding an anterior retroperitoneal approach
- ☐ Active or chronic infection, systemic or infection localized to the operative site
- ☐ Allergy or sensitivity to the implant
- ☐ Bony lumbar stenosis
- ☐ Chronic radiculopathy over a period of at least a year
- ☐ Extruded disc material with sequestrum (i.e. free fragment)
- ☐ Facet joint degeneration
- ☐ Isolated lumbar radiculopathy, especially d/t herniated disc
- ☐ Myelopathy, Pars defect, or Scoliosis
- ☐ Preoperative remaining disc height < 3 mm
- ☐ Spondylolisthesis degenerative or isthmic > than grade 1 segmental instability
- ☐ Osteoporosis or osteopenia defined as DEXA bone mineral density T-score < or equal to -1.0
- ☐ Clinically compromised vertebral bodies at the affected level due to current or past disease (e.g. ankylosing spondylitis) or trauma (fracture)
- ☐ Involved vertebral endplate dimensionally smaller than 31 mm in the medial lateral and/or

The procedure is not comprised of any of the following deemed not medically necessary per your medical policy:

- ☐ Hybrid
- ☐ Multilevel lumbar disc replacement
- ☐ Prior surgery at the treated level

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

☐ Other:
☐ Notes:
Device Requirements:
☐ Must be FDA approved and used per FDA labeling
Enclosures
Enclosed is the following documentation as required by your policy:
☐ Medical records with evidence of 6+ months of failed conservative treatment and DEXA scan results
☐ Documentation of Skeletal Maturity
☐ Radiographs with evidence of degenerative disc disease with one confirmed symptomatic level
Certification and Signature
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.

Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Medica	
Policy Name: Clinical Guidelines Spine Surgery: Lumbar Total Disc Arthroplasty	
Policy Number: III-SUR.34	
Effective Date: January 21, 2019	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

- ☐ Use of an FDA Approved Implant
- ☐ Skeletally mature
- ☐ Individual has documented symptomatic DDD, with or without radicular pain, resulting in unremitting low back pain
- ☐ Documentation of continued episodes of unremitting back pain demonstrating compromised ability to perform routine ADL's
- ☐ Imaging studies/radiological evidence documents a DDD lesion at a level correlating with impaired ADL's
- ☐ BMI is less than 40 at the time of prior auth request
- ☐ Documentation of insertion at one level (L4-5 or L5-S1)
- ☐ Documentation of failure of a minimum of six (6) months of conservative medical management related to current episode/ symptoms
- ☐ Documentation of an Oswestry Disability Index (ODI) score(S) at the conclusion of conservative treatment (e.g. physical therapy regimen, injection therapy) demonstrating one(1) of the following:
  - ☐ Less than 30% improvement in (ODI) score between first and last conservative treatment session
  - ☐ Continued ODI score of greater than or equal to 30% at the conclusion of conservative treatment and thereafter
  - ☐ If the individual has not had conservative treatment and ODI score of greater than or equal to 30% within one month prior to the date of prior authorization request
  - ☐ For an individual unable to complete a minimum of six (6) month of conservative treatment, documentation of one (1) of the following is required
    - ☐ ODI score of greater than or equal to 30% at the time conservative management is discontinued
    - ☐ Inability to perform routine activities of daily living
- ☐ **Does not have any of the following contraindications:**
  - ☐ Moderate to severe facet joint arthritis
  - ☐ Localized or systemic infection
  - ☐ Spinal tumor or other active malignancy
  - ☐ Osteoporosis
  - ☐ Spondylolisthesis

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

☐ Other:
☐ Notes:
Enclosures
Enclosed is the following documentation as required by your policy:
☐ Documentation of continued episodes of unremitting back pain demonstrating compromised ability to perform routine ADL's.
☐ Radiographs with evidence of degenerative disc disease with one confirmed symptomatic level
☐ Documentation of insertion at one level (L4-5 or L5-S1).
☐ Documentation of failure of a minimum of six (6) months of conservative medical management related to current episode/ symptoms.
☐ Documentation of an Oswestry Disability Index (ODI) score(s) at the conclusion of conservative treatment
Certification and Signature
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.

Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Medical Mutual	
Policy Name: Artificial Intervertebral Disc Replacement: Cervical, Thoracic, and Lumbar	
Policy Number: #200813	
Effective Date: October 11, 2017	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

- ☐ 18 or older and skeletally mature;
- ☐ Single level between L4-S1
- ☐ FDA-approved artificial disc (vertebra-specific);
- ☐ Symptomatic lumbar DDD (discogenic back pain with degeneration of the disc confirmed by imaging [CT, MRI, or x-rays)
- ☐ Spondylolisthesis at the involved level per the FDA-approved artificial disc specific limits
- ☐ Candidate for lumbosacral spinal fusion
- ☐ Failure of at least 6 months of conservative treatment, including **ALL** of the following: Physical therapy, anti-inflammatory medication; analgesic medication; avoidance of exacerbating activities

Does not have any of the following contraindications:

- ☐ Allergy or sensitivity to implant materials
- ☐ Active systemic infection or infection at the operative site
- ☐ Osteopenia or osteoporosis (bone density T-score -2.5 or lower measured by dual energy x-ray absorptiometry [DEXA])
- ☐ Moderate to advanced spondylosis characterized by bridging osteophytes, marked reduction or absence of motion, or collapse of the intervertebral disc space of > 50% of its normal height
- ☐ Marked lumbosacral instability on imaging (e.g., signs of subluxation >3.5 mm or angulation of the disc space >11 degrees greater than adjacent segments)
- ☐ Significant kyphotic deformity, significant reversal of lordosis, or significant spondylolisthesis
- ☐ Significant lumbosacral anatomical deformity or compromised vertebral bodies at the index level due to systemic disease, previous surgery, or trauma
- ☐ Severe facet joint arthropathy
- ☐ Symptoms necessitating surgical treatment at > 1 lumbosacral level
- ☐ Congenital stenosis
- ☐ Previous surgery at the involved level
- ☐ Spinal metastases
- ☐ Current medical condition requires long-term use of medications affecting bone quality and fusion rates (e.g., systemic corticosteroids)
- ☐ Nerve root compression
- ☐ Stenosis

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

☐ Other:
☐ Notes:
Device Requirements:
☐ Must be FDA approved and used per FDA labeling
☐ Medical records with evidence of 6+ months of failed conservative treatment
☐ Radiographs with evidence of DDD with one confirmed symptomatic level
Certification and Signature
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.

Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Moda Health	
Policy Name: Intervertebral Disc Prosthesis	
Effective Date: July 1, 2019	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

☐ **FDA-approved lumbar prosthetic intervertebral discs will be covered to plan limitations when ALL of the following criteria are met:**

☐ The patient is skeletally mature

☐ Diagnosis of degenerative disc disease at only one level confirmed by patient history and advanced imaging studies (CT scan or MRI) within the last 6 months

☐ Disc replacement is planned for one level

☐ No more than Grade I spondylolisthesis at the involved level

☐ Patient suffers from low back pain that has not responded to at least 6 months of conservative treatment including all of the following:

- ☐ NSAIDS, analgesics, steroids
- ☐ Physical therapy
- ☐ Epidural steroid injections/selective nerve root blocks

☐ Patient is a candidate for spine surgery (such as a fusion)

☐ No prior lumbar spinal fusion

Patient meets **1 or more** of the following:

☐ Patient is a non-smoker

☐ Patient is a documented smoker and has abstained from tobacco for at least 6 weeks prior to surgery as evidence by lab results documenting (cotinine level) nicotine-free status

Does not have any of the following contraindications:

☐ Previous lumbar fusion

☐ Simultaneous multilevel implantations is planned

☐ Osteoporosis or osteopenia

☐ Imaging studies confirm any of the following conditions:

- ☐ Infection *(active systemic or localized to the site of implantation)*
- ☐ Spinal tumor
- ☐ Multiple levels of degenerative disc disease
- ☐ Degenerative spondylolisthesis of Grade 2 or greater
- ☐ Pars interarticularis defect with either spondylolysis or isthmic spondylolisthesis
- ☐ Severe facet joint arthrosis
- ☐ Nerve root compression or spinal stenosis
- ☐ Scoliosis
- ☐ Spinal fracture

☐ History of chronic steroid use

☐ Pregnancy

☐ Morbid obesity

☐ Known allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene, titanium)

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

☐ Other:
☐ Notes:
Device Requirements:
☐ Must be FDA approved and used per FDA labeling (including any labeling requirements regarding degree of spondylolisthesis)
☐ Single-level use only
Enclosures
Enclosed is the following documentation as required by your policy:
☐ Medical records with evidence of 6+ months of failed conservative treatment
☐ Radiographs with evidence of degenerative disc disease with one confirmed symptomatic level
☐ Tobacco cessation records
Certification and Signature
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.

Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Molina Healthcare	
Policy Name: Artificial Intervertebral Disc Replacement (ADR) Surgery	
Policy Number: MCP-011	
Effective Date: September 13, 2018	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

- ☐ Age 18-60 years old
- ☐ Device is FDA approved for lumbar disc replacement
- ☐ Diagnosis of single level degenerative lumbar disc disease with intractable radiculopathy and/or myelopathy confirmed with imaging studies
- ☐ Symptoms of unremitting back and/or leg pain, resulting in disability and/or neurological deficit refractory to all of the following: Six months or more of standard medical management unless contraindicated:
  - ☐ Activity restrictions and/or;
  - ☐ Exercise; **and**
  - ☐ Analgesics; **and**
  - ☐ Physical therapy
- ☐ The planned implant will be used in the reconstruction of a lumbar disc in only one vertebral level
- ☐ Candidate for single-level lumbar decompression and interbody fusion

Does not have any of the following contraindications:

- ☐ Active systemic infection or infection localized to the site of implantation
- ☐ Allergy or sensitivity to implant materials
- ☐ Bony lumbar stenosis
- ☐ Isolated radicular compression syndromes, especially due to disc herniation
- ☐ Osteopenia
- ☐ Osteoporosis
- ☐ Pars defect

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

☐ Other:
☐ Notes:
Device Requirements:
☐ Must be FDA approved and used per FDA labeling (including any labeling requirements regarding degree of spondylolisthesis)
☐ Single-level use only
Enclosures
Enclosed is the following documentation as required by your policy:
☐ Medical records with evidence of 6+ months of failed conservative treatment
Certification and Signature
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.

Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Paramount	
Policy Name: Artificial Intervertebral Disc Replacement: HMO, PPO, Individual Marketplace & Elite	
Policy Number: PG-0027	
Effective Date: August 25, 2017	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

☐ Skeletally mature

☐ Unremitting low back pain and significant functional impairment is refractory to at least six consecutive months of structured, physician supervised conservative medical management, which includes

ALL of the following components:

- ☐ Exercise, including core stabilization exercises
- ☐ Nonsteroidal and/or steroidal medication (unless contraindicated)
- ☐ Physical therapy, including passive and active treatment modalities
- ☐ Activity/lifestyle modifications

☐ Single-level disc degeneration has been confirmed on complex imaging studies (i.e. CT, MRI)

☐ The implant will be inserted at an FDA approved lumbar/sacral level specific to the implant being used

☐ Elite members must be 60 years of age or younger

☐ **The procedure is not comprised of any of the following deemed not medically necessary per your medical policy**

- ☐ Lumbar artificial disc at more than one level

☐ Other:
☐ Notes:

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Enclosures	
Enclosed is the following documentation as required by your policy:	
☐ Medical records with evidence of 6+ months of failed conservative treatment	
Certification and Signature	
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.	
Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Preferred One	
Policy Name: Intervertebral Disc Prosthesis	
Policy Number: MC/F022	
Effective Date: September 16, 2019	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

- ☐ The member is skeletally mature.
- ☐ The member has low back pain which has failed at least 6 months of conservative treatment within 1 year prior to the scheduled surgery date. The conservative treatment must have included physical therapy.
- ☐ Findings on imaging show either 3mm or less of spondylolisthesis or no more than Grade I spondylolisthesis localized to the disc space being treated
- ☐ Recent imaging has reasonably excluded alternate causes of pain.
- ☐ **Does not have any of the following contraindications:**
  - ☐ Active systemic infection or infection at the operating site
  - ☐ Allergy or sensitivity to any of the implant materials
  - ☐ Any significant lumbar spine deformity at the involved level due to current or past trauma or disease (eg, Ankylosing spondylitis, rheumatoid arthritis); or
  - ☐ Marked lumbar instability on radiographs (eg, radiographic signs of subluxation greater than 3.5mm or angulation of the disc space more than 11 degrees greater than adjacent segments).
  - ☐ Osteopenia or osteoporosis
  - ☐ Severe lumbar facet joint arthropathy
  - ☐ Pars defect/spondylolysis
  - ☐ Stenosis
  - ☐ Leg pain caused by single nerve root compression (aka pinched nerve) [NOTE: Secondary leg pain may be present if it is not isolated]
  - ☐ Nerve root damage (chronic radiculopathy, ie, greater than 1 year), disc fragment that has separated and moved from the disc space, or spinal deformity such as scoliosis
  - ☐ Isolated radicular compression syndromes, especially due to disc herniation
  - ☐ Involved vertebral endplate dimensionally smaller than 34.5 mm in the medial-lateral and/or 27mm in the anterior-posterior directions
- ☐ **The following is considered investigative.**
  - ☐ Intervertebral lumbar disc prosthesis, multi-level.

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

☐ Other:
☐ Notes:
Device Requirements:
☐ Must be used per FDA labeling (including any labeling requirements regarding degree of spondylolisthesis)
Enclosures
Enclosed is the following documentation as required by your policy:
☐ Medical records with evidence of 6+ months of failed conservative treatment
☐ Radiographs with evidence of degenerative disc disease with one confirmed symptomatic level
Certification and Signature
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.

Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

QualChoice	
Policy Name and Number: Intervertebral Disc Prosthesis	
Policy Number: BI 182.00	
Effective Date: December 1, 2018	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

☐ Skeletally mature, **and**
☐ With DDD at one level from L3-S1 confirmed radiologically, **and**
☐ Are symptomatic with radicular pain, **and**
☐ Who have failed at least six months of conservative management
  ☐ NSAIDS, analgesics, steroids
  ☐ Physical therapy
  ☐ Epidural steroid injection/selective nerve root block

☐ To optimize clinical outcomes for this major elective procedure, it is also required:
  ☐ Patient is a non-smoker, OR
  ☐ Patient is a documented smoker and has abstained for at least 6 weeks prior to surgery as evidenced by lab results documenting nicotine-free status (cotinine level)

Does not have any of the following contraindications:
☐ Combined use of a prosthesis and spinal fusion (hybrid)

☐ Other:

☐ Notes:

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Enclosures	
Enclosed is the following documentation as required by your policy:	
☐ Medical records with evidence of 6+ months of failed conservative treatment and DEXA scan results	
☐ Tobacco cessation records if applicable	
Certification and Signature	
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.	
Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Quartz Health System *(formerly known as Gunderson Health System)*	
Policy Name and Number: Artificial Intervertebral Disc Replacement	
Effective Date: January 16, 2019	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

- ☐ Low back pain, resulting in disability and/or neurological deficit that are refractory to at least six (6) months of conservative management for pain relief including ALL the following:
  - ☐ Analgesics, nonsteroidal and/or steroidal medication (unless contraindicated); AND
  - ☐ Application of ice or heat; AND
  - ☐ Physical therapy, including passive and active treatment modalities; AND
  - ☐ Activity/lifestyle modification; AND
- ☐ Single-level disc degeneration is documented and includes BOTH of the following criteria:
  - ☐ The implant procedure includes reconstruction of a single level at any single disc space from L3 to S1; AND
  - ☐ Patient should have no more than a Grade 1 (no more than 3mm) spondylolisthesis at the involved single level.
- ☐ **Does not have any of the following contraindications:**
  - ☐ Use of non- FDA approved lumbar disc prosthesis
  - ☐ The planned procedure includes the combined use of a prosthesis and spinal fusion (i.e., hybrid surgery);
  - ☐ The patient had prior fusion at an adjacent lumbar level;
  - ☐ The patient had prior surgery at the treated level;
  - ☐ Osteopenia, osteomalacia, or osteoporosis (T-score of -3.5, or -2.5, with vertebral crush fracture);
  - ☐ Rheumatoid arthritis or other autoimmune disease;
  - ☐ Paget's disease, osteomalacia or any other metabolic bone disease;
  - ☐ Radiological evidence of ANY of the following:
    - ☐ Significant lumbar anatomical deformity or compromised vertebral bodies at the index level (e.g., ankylosing spondylitis, rheumatoid arthritis, lumbar spinal stenosis or nerve root compression, or compromise due to current or past trauma);
    - ☐ Spinal metastases/tumor.
    - ☐ Skeletal immaturity.
  - ☐ Multi-level lumbar disc arthroplasty.
  - ☐ Use of lumbar prosthetic intervertebral discs (e.g., the activL Artificial Disc, the Charite Artificial Disc, and the ProDisc-L Total Disc Replacement) for lumbarsacral degenerative disc disease.

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

☐ Other:
☐ Notes:
Device Requirements:
☐ Must be FDA approved and used per FDA labeling (including any labeling requirements regarding degree of spondylolisthesis)
☐ Single-level use only
Enclosures
Enclosed is the following documentation as required by your policy:
☐ Medical records with evidence of 6+ months of failed conservative treatment
☐ Documented diagnosis and symptoms of radiculopathy or myelopathy including physical limitations related to the disease
☐ Radiographs with evidence of degenerative disc disease with one confirmed symptomatic level
Certification and Signature
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.

Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

United HealthCare	
Policy Name: Lumbar Artificial Disc Replacement	
Policy Number: 2019T0437V	
Effective Date: July 1, 2019	
Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	
Primary ICD-10-CM Diagnosis Code *(Please Check One)*	
☐ M51.36 Other intervertebral degeneration, lumbar	
☐ M51.37 Other intervertebral degeneration, lumbosacral	
☐ M51.26 Other intervertebral disc displacement, lumbar	
☐ M51.27 Other intervertebral disc displacement, lumbosacral	
☐ Other	
Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*	
☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open	
☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open	
Primary CPT® Procedure Code	
☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar	

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

- ☐ 18 to 60 years old
- ☐ Advanced degenerative disc disease in one vertebral level between L3 and S1 with either moderate to severe degenerative disease or Modic changes
- ☐ Symptoms must correlate with imaging findings
- ☐ No more than Grade 1 Spondylolisthesis at the involved level or any listhesis at two or more lumbar segments
- ☐ Presence of symptoms for at least 6 months
- ☐ Failed at least 6 months of conservative treatment immediately prior to implantation of artificial disc. (including physical therapy, anti-inflammatory medications, analgesics, muscle relaxants and epidural steroid injections)
- ☐ Favorable face to face psychological evaluation

Does not have any of the following contraindications:

- ☐ The procedure is not comprised of any of the following deemed not medically necessary per your medical policy:
  - ☐ Isolated radicular compression syndromes especially due to disc herniation
  - ☐ Spinal stenosis or radiculopathy
  - ☐ Moderate or severe facet arthropathy or pars defect at the operative level demonstrated by MRI scan, CT or plain radiograph
- ☐ Lumbosacral spinal fracture
- ☐ Scoliosis of the lumbosacral spine
- ☐ Active systemic infection or infection localized to site
- ☐ Tumor in the peritoneum, retroperitoneum or site of implantation
- ☐ Osteoporosis or osteopenia as defined by recent (within one year) DEXA scan
- ☐ Previous lumbar spine surgery where the previous surgery destabilized the spine or where the spine at the level of the previous surgery is an alternate source of pain
- ☐ Vascular, urological, or other peritoneal or retroperitoneal pathology that preclude safe and adequate anterior spine exposure
- ☐ The procedure is not comprised of any of the following deemed not medically necessary per your medical policy:
  - ☐ More than one spinal level
  - ☐ Prior history of lumbar fusion or when combined with a lumbar fusion at any level
  - ☐ Treating any other indications not listed above

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

☐ Other:
☐ Notes:
Device Requirements:
☐ Must be FDA approved and used per FDA labeling
☐ Single-level use only
Enclosures
Enclosed is the following documentation as required by your policy:
☐ Medical records with evidence of 6+ months of failed conservative treatment and DEXA scan results
☐ Radiographs with evidence of degenerative disc disease with one confirmed symptomatic level
☐ Behavioral health screening results
Certification and Signature
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.

Surgeon Signature:	Date:

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

Certificate of Medical Necessity

Patient Name:	Surgeon Name:
Surgeon NPI:	
Facility Name:	Facility Tax ID:
Facility Address:	
Facility Type: Inpatient ☐ Outpatient ☐ ASC ☐	

Primary ICD-10-CM Diagnosis Code *(Please Check One)*

- ☐ M51.36 Other intervertebral degeneration, lumbar
- ☐ M51.37 Other intervertebral degeneration, lumbosacral
- ☐ M51.26 Other intervertebral disc displacement, lumbar
- ☐ M51.27 Other intervertebral disc displacement, lumbosacral
- ☐ Other

Primary ICD-10-PCS Procedure Code (if Inpatient) *(Please Check One)*

- ☐ 0SR20JZ Replacement of lumbar vertebral disc with synthetic substitute, open
- ☐ 0SR40JZ Replacement of lumbosacral vertebral disc with synthetic substitute, open

Primary CPT® Procedure Code

- ☐ 22857 Total disc arthroplasty (artificial disc), anterior approach including discectomy to prepare interspace, single interspace, lumbar

Surgeon Certification

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

I certify that this patient meets the criteria for medical necessity as outlined in your medical policy based on the following:

- ☐ Is skeletally mature (18-60)
- ☐ Needs single-level disc replacement with activL (FDA approved artificial disc) as confirmed by imaging, at:
  - ☐ L4-L5 or ☐ L5-S1
- ☐ Has failed at least six (6) months of nonoperative, physician-supervised, conservative treatment
- ☐ Has no more than Grade 1 spondylolisthesis
- ☐ May have some radiologic evidence of degeneration at adjacent levels but without symptoms/pain
- ☐ Has passed a psychological screening for behavioral health disorders
- ☐ Has clinically significant functional impairment (ODI) and pain (VAS)
- ☐ Does not have any of the following contraindications:
  - ☐ Isolated radiculopathy, especially due to herniated disc
  - ☐ Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms extending over a period of at least a year)
  - ☐ Spinal stenosis
  - ☐ Active systemic infection or localized infection near the surgical site
  - ☐ Osteoporosis or osteopenia determined by DEXA scan
  - ☐ Allergy or sensitivity to the implant materials
  - ☐ Extruded disc material with sequestrum
  - ☐ Myelopathy
  - ☐ Spinal deformity, such as scoliosis
  - ☐ Clinically compromised vertebral bodies at the affected level due to trauma or disease
  - ☐ Facet ankylosis or facet joint degeneration
  - ☐ Preoperative remaining disc height < 3 mm

Continued on next page

Certificate of Medical Necessity for Lumbar Total Disc Replacement with the activL® Artificial Disc

☐ Other:
☐ Notes:
Enclosures
Enclosed is the following documentation as required by your policy:
☐ Medical records with evidence of 6+ months of failed conservative treatment and DEXA scan results
☐ My clinical notes
☐ Radiographs with evidence of degenerative disc disease with one confirmed symptomatic level
☐ Behavioral health screening results
Certification and Signature
I certify that I am the surgeon identified on this certificate and that I have completed this form based on my thorough review of the patient's case and on my examination of this patient.

Surgeon Signature:	Date: