Effective October 1, 2010

Dynesys®
Dynamic Stabilization
Reimbursement Kit
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Dynesys Dynamic Stabilization System

The Dynesys Dynamic Stabilization System (Dynesys System) Reimbursement Kit is intended to provide reference material related to general guidelines for the reimbursement of the Dynesys System when used consistently with product's labeling. The Reimbursement Kit includes information regarding coverage, coding and payment as well as guidance regarding insurance verification, prior-authorizations and appeals.

Zimmer offers additional reimbursement resources and tools for orthopedic products and procedures including the Zimmer Reimbursement Hotline, which provides live coding and reimbursement information via dedicated reimbursement specialists. Hotline support is available 8 am to 5 pm eastern, Monday through Friday, at (866) 946-0444.

All Zimmer reimbursement resources referenced above also are available at our web site:  
www.reimbursement.zimmer.com

Product Description

The Dynesys Dynamic Stabilization System uses three proprietary components to stabilize the spine as an adjunct to fusion:

- Titanium screws anchor the system to the spine
- Polycarbonate urethane spacers limit spinal extension
- Polymer cord acts as a tension band to limit spinal flexion

The system is placed under tension creating a dynamic interaction between these components. When the patient bends forward, the cord engages and acts as a tension band and overall flexion is limited. When the patient bends backward, the screw heads interact with the spacer, the spacer resists the compressive load and overall extension is limited.

Summary of Patient Indications

When used as a pedicle screw fixation system in skeletally mature patients, the Dynesys System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, and failed previous fusion (pseudoarthrosis).

In addition, when used as a pedicle screw fixation system, the Dynesys System is indicated for use in patients:

- Who are receiving fusions with autogenous graft only;
- Who are having the device fixed or attached to the lumbar sacral spine; and
- Who are having the device removed after the development of a solid fusion mass.

The Dynesys Dynamic Stabilization System, when used as a pedicle screw fixation system, combines the surgical approach of traditional fusion with the philosophy of dynamic stabilization using flexible materials to stabilize the spine while preserving the anatomical structures. The result is a dynamic stabilization system that allows the surgeon to preserve much of the spinal anatomy.

Payer Coverage

Coverage defines what services and procedures payers will reimburse. Coverage is usually articulated through medical policies and is payer-specific. Payers, including the Centers for Medicare and Medicaid Services (CMS) and private payers, may have different coverage policies for the same procedure. Each payer makes its own determinations of what procedures will and will not be covered.

Because coverage policies can vary by payer, we strongly recommend contacting the payer directly with questions regarding medical policies or guidelines for dynamic spinal stabilization devices. Understanding the prior-authorization requirements for fusion procedures is also recommended, as the Dynesys System is indicated only for use as an adjunct to fusion.

Currently, there are a number of payers with published non-coverage policies for lumbar dynamic stabilization devices. These payers consider dynamic stabilization devices for the treatment of disorders of the lumbar and sacral spine as investigational or not medically necessary for all indications. Please note that the published non-coverage policies are applicable to various dynamic stabilization devices and are not specific to the Dynesys System.

The following payers have published non-coverage policies for dynamic stabilization devices when utilized as an adjunct to fusion. The medical policies listed below are available on the payer's web site. We recommend verifying coverage and reviewing these policies prior to rendering services:
• Aetna
• BlueCross BlueShield of Minnesota
• CareFirst BlueCross BlueShield
• CIGNA
• Great-West Healthcare
• Group Health Cooperative
• Harvard Pilgrim
• Humana
• Medical Health Plans
• MVP Health Preferred Care
• PacificSource
• Premera
• The Regence Group
• United Healthcare
• WellPoint/Anthem

Please note that this list represents payers that currently have medical policies regarding dynamic stabilization and make their policies publicly available. Other payers not listed above may also have coverage policies regarding dynamic stabilization, and we suggest contacting them directly should there be any question regarding their coverage policies.

It may be possible to obtain coverage for the Dynesys System used as a pedicle screw fixation system on a case-by-case basis for some of the members of the payers listed above. A determination of medical necessity will be required and possibly necessitate peer-to-peer discussions with the payer’s medical director. Some examples of members for which a non-coverage policy for treatment with dynamic stabilization devices may not apply are those individuals covered by self-insured employer group health plans and federal employees.

A self-insured group health plan (also known as a self-funded plan) is one in which the employer assumes the financial risk for providing health care benefits to its employees. Self-insured group health plans come under all applicable federal laws, including the Employee Retirement Income Security Act (ERISA). It may be prudent to contact and confirm coverage through the employer and/or the third-party administrator.

The Federal Employee Program (FEP) which is a part of the Federal Employees Health Benefits Program (FEHBP) may dictate that a drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and therefore, coverage eligibility may be assessed on the basis of medical necessity. Contact the FEP to confirm coverage and guidelines for dynamic stabilization devices used as a pedicle screw fixation system.

Medicare has no established coverage policies regarding dynamic stabilization devices used as an adjunct to fusion or otherwise. Medicare will determine case-by-case coverage determinations based upon the necessity and medical reasonability of the treatment for a Medicare beneficiary.

Because of the various issues with private payer coverage for the Dynesys System, the remainder of this reimbursement kit provides guidance regarding typical payer processes including insurance verification, prior-authorization and appealing denied claims. These processes can be confusing and will vary by payer. However, following the guidance provided in this reimbursement kit may help to facilitate achieving case-by-case coverage for the Dynesys System when used as an adjunct to fusion consistent with its indication.

Insurance Verification

Eligibility and Benefits Verification

Understanding and verifying a patient’s insurance eligibility and benefits is a critical process prior to treatment. The eligibility and benefits verification process involves the following three steps:

1. Verifying the patient’s insurance eligibility and benefits prior to treatment by contacting the payer’s provider line number that appears on the patient’s insurance card.

2. Checking with the payer company regarding any patient payment responsibilities including co-payments, deductibles, co-insurance and any other out-of-pocket expenses prior to and post treatment.

3. Informing the patient of their payment responsibilities at the time of appointment scheduling. This step is beneficial to both the patient and the health care provider (HCP). It helps the patient decide on the course of treatment and the HCP to avoid last minute cancellations.
It is important to gather and document information during the insurance verification process for future reference, especially insurer contact information, the patient's financial responsibilities and prior-authorization approval numbers. (See Sample Insurance Verification Form on page 6 and the Insurance Verification Process Flowchart on page 7).

Information That Should Be Obtained From The Insurer And Documented For Future Reference

- Name of insurance representative, including phone number and extension
- Note date and time of call
- Patient's health plan effective and/or termination date
- Type of health plan (HMO, PPO, POS, etc.)
- Patient's financial responsibilities (i.e. co-payment, deductible, out-of-pocket expense)
- In- and out-of-network benefits—this information is important to know because if the treating physician is an out-of-network provider and the plan does not allow out-of-network provider services, the patient may have to seek an in-network provider to perform the procedure. Not knowing this information could lead to a claims denial.
- Verification of benefits for treatment
- Prior-authorization requirements, if any, including contact information (contact name, telephone, fax number)
- Referral requirements, if any, including telephone number and fax number to submit a signed and dated referral from the primary care physician or other referring physician
# Sample Insurance Verification Form

### Patient Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name</td>
<td></td>
</tr>
<tr>
<td>Patient Address</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td></td>
</tr>
<tr>
<td>ST</td>
<td></td>
</tr>
<tr>
<td>Zip</td>
<td></td>
</tr>
<tr>
<td>Home Phone No</td>
<td></td>
</tr>
<tr>
<td>Work Phone No</td>
<td></td>
</tr>
<tr>
<td>Social Security No</td>
<td></td>
</tr>
<tr>
<td>Date of Birth</td>
<td></td>
</tr>
<tr>
<td>M</td>
<td></td>
</tr>
<tr>
<td>F</td>
<td></td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
</tr>
<tr>
<td>Applicable ICD-9-CM Diagnosis code(s)</td>
<td></td>
</tr>
<tr>
<td>Anticipated CPT Code(s) for Procedure(s):</td>
<td></td>
</tr>
</tbody>
</table>

### Patient Eligibility and Benefits Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Date of Coverage</td>
<td></td>
</tr>
<tr>
<td>Coverage Terminated?</td>
<td>Yes [ ] No [ ] Date:</td>
</tr>
<tr>
<td>Plan Type</td>
<td>HMO [ ] PPO [ ] POS [ ] Other:</td>
</tr>
<tr>
<td>In-Network Benefits</td>
<td>$ __________________________</td>
</tr>
<tr>
<td>Co-Payment</td>
<td>$ __________________________</td>
</tr>
<tr>
<td>$ __________________________</td>
<td>Has Deductible Been Met? Yes [ ] No [ ]</td>
</tr>
<tr>
<td>Deductible</td>
<td></td>
</tr>
<tr>
<td>$ __________________________</td>
<td>Other Out-of-Pocket Expense</td>
</tr>
<tr>
<td>Co-insurance</td>
<td></td>
</tr>
<tr>
<td>Benefits for Treatment</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>Is a Referral Necessary?</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>Is Prior-Authorization Required?</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>Out-of-Network Benefits?</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>Out-of-Network Financial Responsibilities?</td>
<td>Yes [ ] No [ ]</td>
</tr>
</tbody>
</table>

### Insurer Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Call Date</td>
<td></td>
</tr>
<tr>
<td>Time of Call</td>
<td></td>
</tr>
<tr>
<td>Name of Insurance Rep</td>
<td></td>
</tr>
<tr>
<td>Phone No / Ext</td>
<td></td>
</tr>
<tr>
<td>Prior-Authorization Phone No</td>
<td></td>
</tr>
<tr>
<td>Fax No</td>
<td></td>
</tr>
<tr>
<td>Prior-Authorization Contact Name</td>
<td></td>
</tr>
<tr>
<td>Prior-Authorization Approval No</td>
<td></td>
</tr>
<tr>
<td>Referral Phone No</td>
<td></td>
</tr>
<tr>
<td>Fax No</td>
<td></td>
</tr>
<tr>
<td>Referral Contact Name</td>
<td></td>
</tr>
<tr>
<td>Notes</td>
<td></td>
</tr>
</tbody>
</table>

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Insurance Verification Flowchart

1. Make a copy of the front and back of the patient’s insurance card.
2. Call the telephone number provided on the back of the patient’s card “to verify coverage.” This is usually a 1-800 number.
3. Ask the eligibility and benefits insurance representative these questions:
   - Does the patient have an effective health plan with the insurance carrier?
     - Yes: What is the effective date of coverage?
     - No: Under what type of plan is the patient covered (e.g., HMO, PPO, POS, etc.)?
6. What is the patient’s co-payment responsibility?
7. Does the patient have a deductible? If yes, how much is the deductible and how much of the deductible has been met?
8. Does the patient have other out-of-pocket expenses? If so, how much?
9. Is the HCP an in-network provider?
10. Does the patient have medical benefits for treatment?
11. Does the treatment require prior-authorization?
12. Is a referral from the primary care physician or other referring physician required?
13. Contact patient to schedule an appointment.
14. Contact patient with results of insurance verification.
15. What is the prior-authorization dept. phone number? Who is my primary contact?
16. Does the referral have to be submitted to payer prior to rendering services? Where do I submit the referral? (List phone and fax number.)
17. Does the patient have out-of-network benefits?
18. Does the patient have medical benefits for treatment?
19. What is the effective date of coverage?
20. If terminated, what is the termination date?
21. Does patient have new insurance card?
22. STOP
Prior-Authorization Process

Medicare

The Medicare program does not provide prior-authorization, prior approval or a predetermination of benefits for any services. General coverage guidelines for many services can be found using the Medicare Coverage Database. The database is maintained by the Centers for Medicare and Medicaid Services (CMS) and is located on the CMS web site at http://www.cms.hhs.gov/mcd/overview.asp. In the absence of a local or national coverage determination, the local carrier will determine whether coverage is available for a service on a case-by-case basis.

An HMO Medicare Advantage program most likely will require prior-authorization of specified services, such as spinal surgery. Please verify prior-authorization guidelines with the payer.

Private Payer

The requirements of private payers for prior-authorization vary. Certain payers may require the health care provider to submit specific patient information for medical review. It is important to become familiar with each payer’s prior-authorization guidelines. (See Prior-Authorization Process Flowchart on page 9).

Prior-authorization means that the insurer has given approval for a patient to receive treatment, a test or surgical procedure before it has actually occurred. A prior-authorization approval does not guarantee payment.

To prior-authorize a procedure before services are rendered, provide the following information to the payer’s prior-authorization department:

• Diagnosis code(s)
• Procedure (CPT®) code(s)
• Description of the procedure
• Product-specific description, if required
• Any additional information requested by the prior-authorization department related to the patient’s condition and procedural clinical evidence

A written prior-authorization request may be required by the payer. (See Appendix B: Sample Letter of Medical Necessity.) The prior-authorization request should include the following detailed information about the patient’s medical condition and the reason for the patient to undergo treatment:

• The patient’s medical condition with exact diagnosis and symptoms associated with the disease
• The medical necessity for the treatment and what health problems may occur if the patient does not undergo the procedure
• What other treatments or services the patient has already had, if any, and why these alternative treatments did not alleviate the symptoms
• A description of the treatment
• Why the procedure is the most appropriate treatment for the patient’s condition

Typically, most payers will respond with a decision within 30 days. The health plan is required to provide a clinical reason for their decision, and whether they are approving or denying the request. If the prior-authorization is approved, document the approval number in the patient’s chart should any questions arise at a later date.

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Prior-Authorization Process Flowchart

HCP prescribes treatment.

Conduct Verification of Eligibility & Benefits
See Insurance Verification Process

Is the patient eligible?

Prior-Authorization Process
» Contact prior-authorization department.
» Complete written prior-authorization request form or prior-authorization letter (sample letter provided in Reimbursement Kit).
» Provide the following to the prior-authorization department: diagnosis code(s), CPT Code(s), description of procedure, product specific description.
» Provide any additional information requested by the prior-authorization department or utilization review nurse.
» Record contact information of the insurance representative including: name, telephone, extension, fax number, and note date and time of call.

Conduct bi-weekly follow-up with payer contact to check on prior-authorization process status.

Is the prior-authorization approved?

Appeal prior-authorization denial?

HCP treats patient.

HCP submits claim to payer.

Is payment received?

YES

Proceed to payment appeals process.

STOP

HCP & Staff
Patient Task

NO

STOP

YES

STOP

NO

STOP

Appeal prior-authorization denial?

YES

Appeal Level 1
» Obtain copy of denial letter from payer or patient (letter contains instructions and contact information).
» Contact payer for clarification of instructions if necessary or if denial can simply be corrected by providing information over telephone.
» Speak to utilization review nurse and/or medical director to address reason for denial, if possible.
» Provide the following documentation to the appeals department:
  • Letter of Medical Necessity (sample letter provided in Reimbursement Kit)
  • Clinical notes
  • Description of procedure
  • Product specific description and clinical information
» See payer communication process

Is Appeal Level 1 approved?

NO

Appeal prior-authorization denial?

YES

Appeal Level 2
» Obtain copy of denial letter from the payer or patient.
» HCP may request peer-to-peer telephone conversation with payer medical director. Call the number on denial letter for instructions.
» Provide the following documentation to the payer appeals department:
  • Letter of Medical Necessity (submit additional clinical data documenting patient's condition and necessity for treatment not previously mentioned in previous correspondence to payer)
  • Additional clinical notes to clarify why treatment is best option for patient
  • Additional clinical data to clarify treatment
» See payer communication process

Is Appeal Level 2 approved?

NO

Appeal prior-authorization denial?

YES

Appeal Level 3
» Obtain copy of denial letter from the payer or patient.
» Appeal Level 3 typically includes a review from an external medical director.
» Request a peer-to-peer telephone conversation with the external medical director. Call phone number on the denial letter for further instructions.
» May require additional clinical data not previously submitted to clarify procedure.
» May require additional clinical notes not previously submitted to clarify patient’s condition and medical necessity.
» See payer communications process.

Is Appeal Level 3 approved?

NO

STOP

STOP

STOP

Patient Action:
If all levels of prior-authorization appeals have been denied by the payer, the patient has options in order to obtain treatment:
» The patient may choose to pay out-of-pocket for the procedure
» If the patient is insured under a self-insured (self-funded) health plan, the patient may seek authorization through the employer
» Patient contacts Department of Labor
» Patient contacts State Insurance Commissioner

Payer Communication Process
» Follow up with payer contact 10-15 days into the process to check status.
» Follow up with payer contact 20-30 days into the process to check status.
» Continue follow-up until final determination.
Most payers will respond with a decision within 30 days.
Coding Guidance for the Dynesys Dynamic Stabilization System

The following pages contain coding guidance for the Dynesys System. The coding guidance is intended to illustrate the CPT® codes, ICD-9-CM procedure codes, and MS-DRG assignments commonly used to describe procedures associated with implantation of the Dynesys Dynamic Stabilization System as a pedicle screw fixation system. This guidance is not intended to be all-inclusive and the listed codes may not be applicable in all cases.

This coding information reflects the use of the Dynesys System as an adjunct to fusion. Any other use of the Dynesys System is not cleared for marketing by the FDA, and this coding guidance does not apply.

Please note that the following coding reference pages do not contain reimbursement information. Individual payment rates will vary by payer contract. Contact your payers for actual payment rates.

**Common Physician Procedure Codes for the Dynesys System**

The following CPT codes may be appropriate to describe procedures associated with the Dynesys System adjunct to fusion with autogenous bone graft. The physician should report the CPT code(s) that best describes the procedure(s) performed.

<table>
<thead>
<tr>
<th>CPT Code*</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20936</td>
<td>Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from same incision</td>
</tr>
<tr>
<td>20937</td>
<td>Morselized (through separate skin or facial incision)</td>
</tr>
<tr>
<td>22612</td>
<td>Arthrodesis, posterior or posterolateral technique, single level; lumbar (with or without lateral transverse technique)</td>
</tr>
<tr>
<td>22614</td>
<td>Each additional vertebral segment. (List separately in addition to code for primary procedure) (Use 22614 in conjunction with codes 22600, 22610, 22612)</td>
</tr>
<tr>
<td>22630</td>
<td>Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar</td>
</tr>
<tr>
<td>22632</td>
<td>Each additional interspace (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>22840&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across one interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation)</td>
</tr>
<tr>
<td>22842&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments</td>
</tr>
<tr>
<td>22849&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Reinsertion of spinal fixation device</td>
</tr>
<tr>
<td>63047</td>
<td>Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root(s), (eg, spinal or lateral recess stenosis), single vertebral segment; lumbar</td>
</tr>
<tr>
<td>63048</td>
<td>Each additional segment, cervical, thoracic, or lumbar. (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

* Commonly used instrumentation codes.

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* Current Procedural Terminology (CPT) is copyrighted 2010 American Medical Association. All Rights Reserved. No fee schedules, basic units, relative values, or related listings are included in CPT. The AMA assumes no liability for the data contained herein. Applicable FARs/DARs restrictions apply to government use.
Common Inpatient Hospital Procedure Codes for the Dynesys System

The following ICD-9 procedure codes may be appropriate to describe procedures associated with the Dynesys System adjunct to fusion with autogenous bone graft.

<table>
<thead>
<tr>
<th>ICD-9 CM Procedure Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>81.07</strong></td>
<td>Lumbar and lumbosacral fusion of the posterior column, posterior technique</td>
</tr>
<tr>
<td><strong>81.08</strong></td>
<td>Lumbar and lumbosacral fusion of the anterior column, posterior technique</td>
</tr>
<tr>
<td><strong>81.37</strong></td>
<td>Refusion of lumbar and lumbosacral spine, posterior column, posterior technique</td>
</tr>
<tr>
<td><strong>81.38</strong></td>
<td>Refusion of lumbar and lumbosacral spine, anterior column, posterior technique</td>
</tr>
<tr>
<td>81.62</td>
<td>Fusion or refusion of 2 – 3 vertebrae</td>
</tr>
<tr>
<td>81.63</td>
<td>Fusion or refusion of 4 – 8 vertebrae</td>
</tr>
<tr>
<td>81.64</td>
<td>Fusion or refusion of 9 or more vertebrae</td>
</tr>
</tbody>
</table>

Common Revenue Codes for the Dynesys System

The following revenue code may be appropriate to describe procedures associated with the Dynesys System adjunct to fusion with autogenous bone graft.

<table>
<thead>
<tr>
<th>Revenue Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0278¹</td>
<td>Medical/surgical supplies and devices – other implants</td>
</tr>
</tbody>
</table>

¹There are no HCPCS codes for the Dynesys System in the inpatient setting. Providers may choose to include on the UB-04 Medicare claim form a Medical/Surgical Supplies and Devices Revenue Code to track charges associated with the device.

Common MS-DRG Assignment for Spine Fusion Procedures

MS-DRG assignment is based in part on ICD-9 procedure codes. The following table lists the most common MS-DRGs related to lumbar and lumbosacral fusion utilizing ICD-9 procedure codes previously described:

<table>
<thead>
<tr>
<th>MS-DRG*</th>
<th>MS-DRG Description</th>
<th>Medicare 2010 Relative Weight¹</th>
<th>Estimated Base Payment²</th>
</tr>
</thead>
<tbody>
<tr>
<td>459</td>
<td>Spinal Fusion Except Cervical with MCC</td>
<td>6.5065</td>
<td>$36,333</td>
</tr>
<tr>
<td>460</td>
<td>Spinal Fusion Except Cervical without MCC</td>
<td>3.8713</td>
<td>$21,618</td>
</tr>
</tbody>
</table>


²42 CFR Parts 411, 412, 413, 422, and 489 Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2011 Rates; Payments for Graduate Medical Education in Certain Emergency Situations; Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; Updates to the Long-Term Care Prospective Payment System; Updates to Certain IPPS Excluded Hospitals; and Collection of Information Regarding Financial Relationships Between Hospitals; Final Rule, August 16, 2010.

**FY2011 Revised ICD-9 procedure code titles effective October 1, 2010**
**Appeals**

**Appealing Denials**

An appeal is a request for review of a denied claim or service. Claims may be denied for many reasons, including the result of health plan errors, inaccurate patient or claim information submission, inaccurate coding or health plan coverage policy. Prior-authorization is typically denied because the payer could not determine the medical necessity and appropriateness of the proposed treatment, level of care assessment and/or appropriate treatment setting or the services are deemed experimental or investigational. The reason for the denial can be found in the denial letter and/or the explanation of benefits (EOB). If a claim or service is denied, an appeal may be filed with the insurance carrier. (See **Appealing Denials Process Flowchart** on page 15).

Depending on the payer, the level of appeal may be considered a reconsideration, redetermination, grievance or an appeal. Each payer may have differing administrative requirements for each of these depending on their own definitions. Because payers have different appeal processes, we suggest contacting the payer directly to verify their appeal requirements.

Some payers have specific forms, phone numbers and addresses that must be used to submit an appeal. Please contact your payer to see if there is an identifiable appeal process that should be followed. Payer-specific guidelines for appeals may also be found online. If a payer has a standard appeal form, fill it out and submit it with all other supporting documentation that proves the need for coverage.

The following are some suggested questions to ask the insurance representative regarding their specific appeals process:

- Does the appeal request have to be completed by the health care provider or the patient?
- Is there a particular form that needs to be completed?
- Can this form be faxed or mailed?
- If faxed, what is the fax number?  If mailed, what is the appropriate address?
- Is a letter of medical necessity required?
- What is the time limit for requesting an appeal?

When requesting a review of the denied claim or service, the request must meet the following requirements:

- The request must be in writing.
- Include reasons why the denial is incorrect
- Include any new and relevant information not previously submitted, such as the procedure dictation notes

- Must be requested within the period of time allotted by the payer’s guidelines. Please be advised that the appeal guidelines and timeframes are provided in the letter of denial. If the denial letter is not readily available, contact the payer’s appeal department for instructions.

If the payer does not have a required appeal form, submit an appeal letter (See Appendix C: Sample Prior-Authorization Appeal Letter and Appendix D: Sample Appeal Claims Denial Letter). The appeal letter should be tailored to the reason for the denial and may include a corrected claim, product information, patient medical information, clinical data, and/or economic data along with other supporting documentation.

The Centers for Medicare and Medicaid Services (CMS) defines medical necessity as those services that are reasonable and necessary for the diagnosis or treatment of an illness or injury. The term medical necessity is usually used to determine whether or not a procedure or service is covered by CMS. The appropriate diagnosis, treatment and follow-up care plan, as determined and prescribed by the health care provider, should fit the patient’s specific diagnosis. To establish medical necessity, the physician must clearly describe the condition(s) that justify the medical service provided.

The more complete and detailed an appeal is, the more successful it is likely to be. That is, the specificity of the medical necessity information and the documentation provided are key to the success of the appeal. It is critical to the appeal process that the health care provider attach any medical documentation that may support the medical necessity of the services being provided.
The supporting medical documentation listed below is an example of the type of information that may be submitted in order to support the claim for payment or a service for approval:

- Physician’s order
- Medical history
- Physician’s notes/nurse’s notes
- Procedure dictation notes
- Test results
- X-ray reports
- Consultation reports
- Plan of treatment
- Referrals
- Product information
- Specific reasons the physician believes that the use of the Dynesys System is medically necessary
- Relevant clinical data
- List of conservative or alternative treatments that failed
- Discharge notes

If the claim or service is denied by the insurer’s internal department and the intent is to continue the process of either obtaining a prior-authorization or appealing a denied claim, state-specific and payer-specific guidelines must be followed to elevate the appeal to a higher level. The type of insurance determines whether federal or state laws apply to the appeal process. If the plan is self-funded through an employer group then the Employee Retirement and Income Security Act (ERISA) applies and the Department of Labor has jurisdiction. If it is commercial insurance, state law applies and the state Division of Insurance (DOI) has jurisdiction.
Appealing Denials Process Flowchart

**HCP Receives Claim or Service Denial From Payer**

- **Appeal Denial?**
  - NO → STOP
  - YES → Appeal Denial?

**Appeal Denial?**

- NO → STOP
- YES → Appeal Level 1 (Internal Review)

**Appeal Level 1 (Internal Review)**

- Timelines to appeal are payer-specific. Contact the payer to confirm the timing requirements to file an appeal.
  - Obtain Explanation of Benefits (EOB) showing payment denial from payer or patient, or prior-authorization denial letter. (Both the EOB and the denial letter contain the reason(s) for the denial.)
  - Call payer appeals department for further instructions or clarification, if necessary.
  - Provide the following documentation to the appeals department:
    - Letter of Medical Necessity
    - Procedure Dictation Notes and Clinical Notes
    - Description of Procedure
    - Appropriate Coding
  - Timeline varies by payer.
  - See payer communication process.

- Appeal payment denial?
  - NO → STOP
  - YES → Appeal Level 2 (Internal Review)

**Appeal Level 2 (Internal Review)**

- Request copy of denial letter.
- If necessary, contact payer appeals department for further instructions or clarification.
- Request instructions for a peer-to-peer conversation with medical director.
- Provide additional medical notes not previously submitted to demonstrate medical necessity (if available).
- Provide additional clinical data not previously submitted for clarification (if available).
- Timeline varies by payer.
- See payer communication process.

- Appeal payment denial?
  - NO → STOP
  - YES → Appeal Level 3 (External Review)

**Appeal Level 3 (External Review)**

- Request copy of denial letter.
- Contact the payer appeals department for instructions for an external appeal. These instructions will vary by payer.
- Request instructions for a peer-to-peer conversation with medical director.
- Provide additional clinical notes and data not previously submitted as requested by medical director.
- Timeline and authorization varies by payer.
- See payer communication process.

- Appeal payment denial?
  - NO → STOP
  - YES → All levels of appeals have been exercised. There are no further actions for the HCP to take with the payer to obtain payment for treatment.

**Payment Received**

- YES → Is Appeal Level 1 approved?
  - NO → Appeal payment denial?
    - NO → STOP
    - YES → Appeal Level 2 (Internal Review)
  - YES → Appeal Level 1 approved?
    - NO → STOP
    - YES → Appeal Level 2 approved?
      - NO → Appeal payment denial?
        - NO → STOP
        - YES → Appeal Level 3 (External Review)
      - YES → Appeal Level 3 approved?
        - NO → Appeal payment denial?
          - NO → STOP
          - YES → All levels of appeals have been exercised. There are no further actions for the HCP to take with the payer to obtain payment for treatment.
        - YES → All levels of appeals have been exercised. There are no further actions for the HCP to take with the payer to obtain payment for treatment.
      - YES → All levels of appeals have been exercised. There are no further actions for the HCP to take with the payer to obtain payment for treatment.

**Patient Action**

If all levels of payment appeals have been denied by the payer, the patient has two options to continue the appeal process:

**ERISA, if eligible:** The employee Retirement Income Security Act (ERISA). A plan member becomes eligible for ERISA because employee benefits are provided through a private employer. The patient contacts Department of Labor.

**Patient contacts insurance commissioner in the state that he or she resides.**

Legend

- HCP & Staff Task
- Patient Task
Frequently Asked Questions

1. How do I know if a service or procedure will be covered by the patient’s insurance carrier?
   
   Answer: Coverage policies vary by payer. Payers may make medical policies available to providers to articulate which procedures are covered. Contact the payer directly with questions regarding medical policies or guidelines for dynamic stabilization devices.

2. Can a health care provider request a prior-authorization from a payer with an existing non-coverage policy for the treatment?
   
   Answer: Yes – the health care provider can request a prior-authorization for treatments that fall under a non-coverage medical policy for a payer. Please note that the chance of denial is higher for these services, and the health care provider must place a greater emphasis on articulating why the procedure is medically reasonable and necessary for the specific patient they intend to treat.

3. Are there any options for getting the Dynesys System approved for patients with payers that have published non-coverage policies for dynamic stabilization?
   
   Answer: The Dynesys System is indicated only for use as an adjunct to fusion. It may be possible to obtain coverage on a case-by-case basis from insurers that have established non-coverage policies. The chance of prior-authorization denial is higher for these services, and the health care professional must place a greater emphasis on articulating why the procedure is medically reasonable and necessary for the specific patient they intend to treat. (See Appendix B: Sample Letter of Medical Necessity)

   Non-coverage policies for treatment with dynamic stabilization devices may not apply to those individuals covered by health plans under the Federal Employee Program (FEP) or self-funded plans that come under the Employee Retirement Income Security Act (ERISA). It is recommended that the health care provider and/or the patient contact the FEP or the employer and/or the third-party administrator for guidelines and instructions.

4. Will Medicare give prior-authorization for spine surgery?
   
   Answer: The Medicare program does not give prior-authorization, prior approval or a predetermination of benefits for any services. General coverage guidelines for many services can be found using the Medicare Coverage Database. The Medicare coverage guidelines are posted on the CMS web site.

5. Does the physician have to demonstrate medical necessity when appealing a denied claim or service?
   
   Answer: Yes – It is strongly recommended that the physician demonstrate medical necessity when requesting an appeal of a denied claim or service. To establish medical necessity, the physician must clearly describe the condition(s) that justify why the medical procedure should be provided. The more complete and detailed description provided by the physician increases the probability of overturning the denied claim or service.

6. If I get a prior-authorization approval, will I get paid for the procedure?
   
   Answer: Prior-authorization means that the insurer has given approval for a patient to receive a treatment, test or surgical procedure before it has actually occurred. The intent is to determine medical necessity and appropriateness of the proposed treatment and the appropriate treatment setting. A prior-authorization approval does not guarantee payment.

7. What is the patient’s financial responsibility for a spinal surgical procedure?
   
   Answer: In order to determine the patient’s financial responsibilities, contact the patient’s insurance plan by calling the number on the patient’s insurance card to verify co-payment, deductible, and any other out-of-pocket expenses.

8. Why do I need to know if the patient has out-of-network benefits?
   
   Answer: It is important to know if a patient has out-of-network benefits because if the treating physician is an out-of-network provider and the plan does not allow out-of-network provider services, the services may be denied. In such cases the patient will need to find an in-network provider to perform the services.
9. Can I appeal a denied prior-authorization request?

Answer: Yes, a denial for a prior-authorization request can be appealed. It is important to address the reason for denial in the prior-authorization appeal letter. The reason for the denial is found in the prior-authorization denial letter. Contact the payer for specific appeal instructions.

10. How do I code for the Dynesys System as an adjunct to fusion with autogenous graft?

Answer: Health care providers should select the procedure code(s) they feel most appropriately describe the services provided when using the device. Responsibility for correct coding lies with the service provider. The Zimmer Reimbursement Hotline, which provides live coding information via dedicated reimbursement specialists, is available 8 am to 5 pm eastern, Monday through Friday at (866) 946-0444. Zimmer also offers a Dynesys® Dynamic Stabilization System Reimbursement and Coding Reference Guide at www.reimbursement.zimmer.com.

11. How do I know the reason why a claim has been denied?

Answer: The claims denial letter contains the reason(s) for the denial as well as instructions for the appeal. The denial code(s) can be found on the explanation of benefits. The explanation of benefits does not contain instructions for appeal. Contact the payer for specific instructions to appeal the claim.

12. I have exhausted all of my options for appealing a denial. Are there any other steps available to continue the process of obtaining an approval for coverage?

Answer: There are state-specific and payer-specific guidelines that must be followed to elevate the appeal to a higher level. The type of insurance determines whether federal or state laws apply to the appeal process. If the plan is self-funded through an employer group then the Employee Retirement and Income Security Act (ERISA) applies. If it is commercial insurance, state law applies and the state Division of Insurance (DOI) has jurisdiction.
Appendix A
Sample Letter of Prior-Authorization Request and Medical Necessity

(Date)

(Contact Name)
(Title)
(Insurance Company Name)
(Address)
(City, ST Zip Code)

Re: (Patient’s Name)
Date of Birth:
Group Number:
Subscriber/Policy Number:

Dear (Contact Name):

I am requesting prior-authorization and a determination of medical necessity for (Patient’s Name) who suffers from (Insert Diagnosis).

As you know, (Patient’s Name) was diagnosed with (Diagnosis) on (Insert Date). This patient also has (List the symptoms or co-morbidities). (Include further information about the patient here: attempted conservative or alternative treatments that have failed and what health problems may occur if the patient does not undergo the procedure. Describe anticipated outcomes and the medical benefits of the treatment). Currently, I believe that (Patient’s Name) will significantly benefit from (Procedure Name).

The Dynesys Dynamic Stabilization System uses three components to stabilize the spine as an adjunct to fusion. They include titanium screws that anchor the System to the spine, polycarbonate urethane spacers that limit spinal extension and a polymer cord that acts as a tension band to limit spinal flexion. The System is placed under tension creating a dynamic interaction between the components. When the patient bends forward, the cord engages and acts as a tension band and overall flexion is limited. When the patient bends backward, the screw heads interact with the spacer, the spacer resists the compressive load and overall extension is limited.

The benefits of using the Dynesys System instead of a traditional rod as an adjunct to fusion include:

- Anatomy Preservation – Because the Dynesys System is placed low and lateral, the patient’s facet joints and natural disc can be preserved
- Patient-specific – Spacers are cut to match the patient’s individual anatomy, allowing spinal segments to remain in a more natural position during the fusion process

I ask that you consider authorizing this procedure and would appreciate your immediate response to this matter. The procedure is scheduled for (Insert Date). If you would like to further discuss this matter, please contact me at (Physician’s Telephone Number). Please feel to fax to me the prior-authorization approval at (Physician’s Office Fax Number). I look forward to your response.

Sincerely,
(Physician’s Signature)
(Practice Name)
Appendix B
Sample Letter of Medical Necessity

(Date)

(Contact Name)
(Title)
(Insurance Company Name)
(Address)
(City, ST Zip Code)

Re: (Patient's Name)
Date of Birth:
Group Number:
Subscriber/Policy Number:

Dear (Contact Name):

This letter is written on behalf of (Patient's Name) to document the medical necessity of (Procedure Name) for the treatment of (Patient's Diagnosis). This letter provides information about the patient’s medical history and treatment.

(Insert information regarding the patient's condition and history. Include information on treatments that have been tried and failed. Describe the anticipated outcome without treatment and the medical benefit of treatment based on clinical points supported in the clinical research and/or medical literature.)

The Dynesys Dynamic Stabilization System uses three components to stabilize the spine as an adjunct to fusion. They include titanium screws that anchor the System to the spine, polycarbonate urethane spacers that limit spinal extension and a polymer cord that acts as a tension band to limit spinal flexion. The System is placed under tension creating a dynamic interaction between the components. When the patient bends forward, the cord engages and acts as a tension band and overall flexion is limited. When the patient bends backward, the screw heads interact with the spacer, the spacer resists the compressive load and overall extension is limited.

The benefits of using the Dynesys System instead of a traditional rod as an adjunct to fusion include:
• Anatomy Preservation – Because the Dynesys System is placed low and lateral, the patient’s facet joints and natural disc can be preserved
• Patient-specific – Spacers are cut to match the patient’s individual anatomy, allowing spinal segments to remain in a more natural position during the fusion process

In summary, (Procedure Name) is medically necessary and appropriate to treat (Patient’s name) at this stage in (his or her) course of care. I am enclosing documentation supporting the medical necessity for the course of treatment for this patient. I urge you to provide coverage at this time. Please contact me at (Physician’s Telephone Number) if you require additional information or would like to discuss the case in greater detail.

Sincerely,
(Physician’s Signature)
(Practice Name)

Enclosures:
Appendix C
Sample Prior-Authorization Appeal Letter

(Date)

(Contact Name)
(Title)
(Insurance Company Name)
(Address)
(City, ST Zip Code)

Re: (Patient’s Name)
Date of Birth: 
Group Number: 
Subscriber/Policy Number: 

Dear (Contact Name):

Please accept this letter as my request to appeal to (Insurance Company Name)’s prior-authorization denial for (State the name of the specific procedure denied). It is my understanding based on your letter of denial dated (Insert Date) that this procedure has been denied because (Quote the specific reason for the denial stated in the denial letter).

I believe that (Procedure Name) is a medically necessary treatment for this patient with (Patient’s Condition). This letter provides information about the patient’s medical history and diagnosis, and my rationale for this course of treatment.

The history and clinical course for (Patient’s name) are as follows: (Insert information concerning the patient’s condition, medical history and clinical course prior to treatment with denied therapy. Include the physician’s rational for selected therapy).

The Dynesys Dynamic Stabilization System uses three components to stabilize the spine as an adjunct to fusion. They include titanium screws that anchor the System to the spine, polycarbonate urethane spacers that limit spinal extension and a polymer cord that acts as a tension band to limit spinal flexion. The System is placed under tension creating a dynamic interaction between the components. When the patient bends forward, the cord engages and acts as a tension band and overall flexion is limited. When the patient bends backward, the screw heads interact with the spacer, the spacer resists the compressive load and overall extension is limited.

The benefits of using the Dynesys System instead of a traditional rod as an adjunct to fusion include:

• Anatomy Preservation – Because the Dynesys System is placed low and lateral, the patient’s facet joints and natural disc can be preserved
• Patient-specific – Spacers are cut to match the patient’s individual anatomy, allowing spinal segments to remain in a more natural position during the fusion process

I urge you to grant prior-authorization for (Patient’s Name) for the treatment of (Diagnosis) with (Procedure Name) promptly. Please feel free to contact me at (Physician’s Telephone Number), if you require additional information.

Sincerely,

(Physician’s Signature)
(Practice Name)
Appendix D
Sample Appeal Claims Denial Letter

(Date)

(Contact Name)
(Title)
(Insurance Company Name)
(Address)
(City, ST Zip Code)

Re: (Patient's Name)
Date of Birth:
Group Number:
Subscriber/Policy Number:

Dear (Contact Name):

I am writing in response to your denial of the enclosed claim for date of service (Insert Date) for (Procedure Name) to treat (Diagnosis). (Insert insurance company name) has denied payment for this treatment for (Patient's Name) for the following reason(s) listed on the attached (denial letter or explanation of benefits): (List the denial reason(s) on the denial letter or the EOB reason(s) denial code(s) and definition). I am submitting the claim for reconsideration. This letter provides information about the patient’s medical history and diagnosis, and statement summarizing my treatment rationale.

(Procedure Name) is a (Briefly describe the procedure) for the treatment of (Diagnosis). The history of (Mr./Mrs.) (Patient's Last Name)’s condition is as follows:

(Discuss the patient’s diagnosis, treatment history, cause and degree of illness. List conservative or alternative treatments that failed and the reason the symptoms were not alleviated. Describe the medical benefits of the treatment and the anticipated outcomes. Summarize the need for the treatment.)

The Dynesys Dynamic Stabilization System uses three components to stabilize the spine as an adjunct to fusion. They include titanium screws that anchor the System to the spine, polycarbonate urethane spacers that limit spinal extension and a polymer cord that acts as a tension band to limit spinal flexion. The System is placed under tension creating a dynamic interaction between the components. When the patient bends forward, the cord engages and acts as a tension band and overall flexion is limited. When the patient bends backward, the screw heads interact with the spacer, the spacer resists the compressive load and overall extension is limited.

The benefits of using the Dynesys System instead of a traditional rod as an adjunct to fusion include:
• Anatomy Preservation – Because the Dynesys System is placed low and lateral, the patient’s facet joints and natural disc can be preserved
• Patient-specific – Spacers are cut to match the patient’s individual anatomy, allowing spinal segments to remain in a more natural position during the fusion process

In summary, the procedure is medically necessary and reasonable for (Mr./Mrs.) (Patient's Last Name)’s condition and warrants coverage. I am enclosing documentation supporting the medical necessity for this treatment. Please contact me at (Physician’s Telephone Number) if you would like to further discuss this matter.

Sincerely,
(Physician’s Signature)
(Practice Name)

Enclosures:
DISCLAIMER

The information presented in this reimbursement kit is intended for informational purposes only, and nothing herein is advice, legal advice or a recommendation of any kind, and it should not be considered as such. The coding and coverage information in this reimbursement kit was obtained from third party sources and is subject to change without notice, including as a result in changes in reimbursement laws, regulations, rules and policies. Reimbursement kit content is informational only, general in nature, and does not cover all situations or all payers’ rules or policies, and is not intended to apply to any particular situation. The service and the product must be reasonable and necessary for the care of the patient to support reimbursement. Providers should report the procedure and related codes that most accurately describe the patient’s medical condition, procedures performed and the products used. The information presented in this reimbursement kit represents no promise or guarantee from Zimmer regarding coverage or payment for products or procedures by Medicare or other payers. Providers should check Medicare bulletins, manuals, program memoranda, and Medicare guidelines to ensure compliance with Medicare requirements. Inquiries can be directed to the hospital’s Medicare Part A fiscal intermediary, the physician’s Medicare Part B carrier, the applicable Medicare Administrative Contractor (MAC), or to appropriate payers. Zimmer specifically disclaims liability or responsibility for the results or consequences of any actions taken in reliance on information presented in this reimbursement kit.

This Reimbursement Kit is effective October 1, 2010 to December 31, 2010

Contact the Zimmer Reimbursement Hotline at 866-946-0444
or visit us at www.reimbursement.zimmer.com