

REIMBURSEMENT GUIDE

IMPORTANT SAFETY INFORMATION

Indication

HYMOVIS® is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy or simple analgesics (eg, acetaminophen).

Important Safety Information

HYMOVIS® is contraindicated in patients with known hypersensitivity to hyaluronate preparations or gram positive bacterial proteins or patients with infections/skin diseases in the area of the injection site/joint. The safety and effectiveness of HYMOVIS® has not been tested in pregnant women, nursing mothers or children. See package insert for full prescribing information including adverse events, warnings, precautions, and side effects at www.HYMOVIS.com.

Rx Only

See package insert for full prescribing information including indications, contraindications, warnings, precautions, and adverse events.

Please see full Prescribing Information at www.HYMOVIS®.com.



The HYMOVIS® Support Hotline does not file claims or appeal claims for callers, nor can it guarantee that you will be successful in obtaining reimbursement. Third-party payment for medical products and services is affected by numerous factors, not all of which can be anticipated or resolved by the Hotline.

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INTRODUCTION

Description and Indication

HYMOVIS® (high molecular weight viscoelastic hyaluronan) is a sterile, non-pyrogenic, viscoelastic hydrogel contained in a single-use syringe. HYMOVIS® is based on an ultra-pure hyaluronan engineered using a proprietary process to increase viscosity, elasticity, and residence time without chemical crosslinking. This results in a natural hyaluronan similar to the hyaluronan found in the synovial fluid present in the human joint. The hyaluronan in HYMOVIS® is derived from bacterial fermentation.

HYMOVIS® is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy or simple analgesics (eg, acetaminophen).

Please see full Prescribing Information at www.HYMOVIS®.com.

Dosage and Administration

HYMOVIS® is supplied in 1 box containing 2 single-use 5 mL syringes, each containing a 3 mL dose of HYMOVIS® to be injected 1 week apart. HYMOVIS® is intended to be injected into the knee joint and is administered as a regimen of 2 intra-articular injections.

Using the HYMOVIS® Reimbursement Guide

This guide is designed to serve healthcare professionals as a reference for general coding and claims information related to HYMOVIS®. There are many factors that affect how payers will cover and pay for HYMOVIS®, including the site of service where it is administered, what type of health insurance the patient has, and the type of benefits the payer offers. This guide contains the following information:

Coding for HYMOVIS® by site of service, including coding for the diagnosis and administration procedure

HYMOVIS® Support Hotline services and contact information

Prior Authorization checklist

Sample claim forms that illustrate the key components that may be required by a payer when completing a claim for HYMOVIS®

Tips for submitting clean claims and strategies to appeal denied claims



DISCLAIMER

Information described in the HYMOVIS® Reimbursement Guide is intended solely for use as a resource tool to assist physician office, hospital outpatient, and ambulatory surgical center billing staff regarding reimbursement issues. Any determination regarding if and how to seek reimbursement should be made only by the appropriate members of the staff, in consultation with the physician, and in consideration of the procedure performed or therapy provided to a specific patient. FIDIA FARMACEUTICI S.P.A/FIDIA PHARMA USA INC. does not recommend or endorse the use of any particular diagnosis or procedure code(s) and makes no determination if or how reimbursement may be available. Of important note, reimbursement codes and payment, as well as health policy and legislation, are subject to continual change; information contained in this version of the HYMOVIS® Reimbursement Guide is current as of July 2018.

Information provided in the HYMOVIS® Reimbursement Guide is for your guidance only. The *HYMOVIS® Support Hotline* does not file or appeal claims for callers, nor can it guarantee reimbursement by third-party payers. For details on the specific services provided by the *HYMOVIS® Support Hotline*, please see the following section of the HYMOVIS® Reimbursement Guide. Reimbursement specialists at the *HYMOVIS® Support Hotline* are available to assist you with questions related to reimbursement support and access services for therapy with HYMOVIS® at 1-866-HYMOVIS (1-866-496-6847), Monday through Friday, from 9:00 AM to 8:00 PM ET.



OVERVIEW OF REIMBURSEMENT SUPPORT PROGRAM

HYMOVIS® Support Hotline

Coverage and coding for HYMOVIS® (high molecular weight viscoelastic hyaluronan) may vary depending on the patient's type of health insurance and the site of service where the product is administered (ie, physician office, hospital outpatient department, or ambulatory surgical center). It will be important to conduct a benefit investigation for each patient in order to verify the following:

Coverage and utilization restrictions, such as Prior Authorization, for HYMOVIS®

Patient copayment or coinsurance for HYMOVIS® and administration services

Coding for HYMOVIS®

Provider's network status with plan

Upon request, the *HYMOVIS®* Support Hotline will provide Prior Authorization support by submitting, if possible, any of the information available for a verbal Prior Authorization if the payer will accept it from the *Hotline*.

HYMOVIS® Support Hotline offers comprehensive reimbursement assistance to practices, ambulatory surgical centers, and hospital providers. Reimbursement counselors are available to support healthcare professionals with questions and the following support services:



Patient-specific benefit verification for medical and specialty pharmacy benefits



Coding and billing support



Comprehensive Prior Authorization support



Alternative coverage research



Claims management



Appeals assistance



Specialty pharmacy triage, upon request



OVERVIEW OF REIMBURSEMENT SUPPORT PROGRAM (CONT.)

HYMOVIS® Support Hotline provides timely information to healthcare professionals in order to expedite patient access to care. In fact, most reimbursement research requests can be completed in 1 to 2 business days from the time complete information is submitted to the Hotline.

It is helpful to have the following information available when calling the *Hotline* to speak with a reimbursement counselor:



Physician's name, address, phone number, and provider number (NPI, TID, etc)



Policy identification and group numbers



Patient's name, date of birth, address, and Social Security number



Diagnosis



Insurance company name, phone number, and fax number



Site of care



Name of policy holder



Office contact name and phone number

In addition to reimbursement assistance, the HYMOVIS® Support Hotline will work with you and your patients to provide additional resources that may include the following:

- Patient case management services
- Product ordering management

In order to access services available through the <code>HYMOVIS®</code> Support Hotline, healthcare professionals and their patients are asked to fill out and sign a benefit verification request form. You can obtain the form by contacting the <code>HYMOVIS®</code> Support Hotline, accessing it on the www.HYMOVIS.com website, or requesting one from your Fidia Pharma sales representative.





CODING FOR HYMOVIS (HIGH MOLECULAR WEIGHT VISCOELASTIC HYALURONAN) AND ASSOCIATED SERVICES

Coding for HYMOVIS®

Most payers recognize Healthcare Common Procedure Coding System (HCPCS) Level II national codes to identify and report products (drugs and medical devices), supplies, and services not included in the Current Procedural Terminology (CPT) code.

For HYMOVIS®, payers accept the following HCPCS code:

| HCPCS Code | Description | Billing Units | Site of Service | Claim Form (Location) | Payer Type |
|---------------|--|---|---|--------------------------|---------------|
| | Hyaluronan | 24 | Physician Office | CMS-1500 (Box 24D) | |
| J7322 | or derivative, HYMOVIS, for intra-articular injection, 1 mg | (1 mg = 1 billing unit Each syringe = 24 billing units) | Hospital outpatient CMS-1450 (Field 44) | All | |
| | | | Ambulatory surgical center | CMS-1450 (Field 44) | |

HYMOVIS® is supplied in a 5 mL single-use syringe containing 3 mL of HYMOVIS®

- Each mL has 8 mg of hyaluronan
- 3 mL has 24 mg of hyaluronan
- HYMOVIS® <u>administration does not vary</u> by patient
 - Uniform administration for all patients

Medicare reimburses HYMOVIS® at WAC+6%

Source: Medicare Claims Processing Manual Chapter 17 (Rev. 3932, 12-08-17) Transmittal 20.1.3 https://www.cms.gov/Regulations-and Guidance/Guidance/Manuals/Downloads/clm104c17.pdf. Contact private payers or consult contracts for their reimbursement amounts.

Catalog Number (also known as the NHRIC)

For devices such as HYMOVIS®, the manufacturer adopts a unique, 3-segment catalog number sometimes referred to as the national-related items code (NHRIC). Proper billing, especially to Medicare, Medicaid, or via electronic data interchange, requires the catalog number to be submitted in the 11-digit numeric 5-4-2 format (eg, 89122-0496-63). Do not use hyphens when entering the actual data on your claim. For example:

| HYMOVIS® 11-digit Example | Reporting on CMS Claim Forms |
|---------------------------|------------------------------|
| 89122-0496-63 | 89122049663 |



Coding for Administration Services

CPT codes are used to identify professional services (eg, administration procedure) provided in the physician office.

| CPT Code | Description |
|----------|--|
| 20610 | Arthrocentesis, aspiration, and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance |
| 20611 | Arthrocentesis, aspiration, and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); with ultrasound guidance |

| Modifier | Modifier Description |
|----------|---|
| RT | Right side (used to identify procedures performed on the right side of the body) |
| LT | Left side (used to identify procedures performed on the left side of the body) |
| 50 | Bilateral procedure |
| EJ | Indicates subsequent injections of a series. Do not use for first injection of each series. |

ICD-10-CM Diagnosis Codes

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis codes are used to report diseases and conditions. ICD-10-CM diagnosis codes identify why a patient needs treatment by documenting the medical necessity for prescribing HYMOVIS®. Coding to the highest level of specificity may expedite the claims adjudication process. The following ICD-10-CM diagnosis codes may be appropriate to describe patients with OA of the knee.

| ICD-10-CM | Description | | |
|-----------|--|--|--|
| M17.0 | Bilateral primary osteoarthritis of knee | | |
| M17.10 | Unilateral primary osteoarthritis, unspecified knee | | |
| M17.11 | Unilateral primary osteoarthritis, right knee | | |
| M17.12 | Unilateral primary osteoarthritis, left knee | | |
| M17.2 | Bilateral post-traumatic osteoarthritis of knee | | |
| M17.30 | Unilateral post-traumatic osteoarthritis, unspecified knee | | |
| M17.31 | Unilateral post-traumatic osteoarthritis, right knee | | |
| M17.32 | Unilateral post-traumatic osteoarthritis, left knee | | |
| M17.4 | Other bilateral secondary osteoarthritis of knee | | |
| M17.5 | Other unilateral secondary osteoarthritis of knee | | |
| M17.9 | Osteoarthritis of knee, unspecified | | |

Coding for HYMOVIS® may vary by payer type and plan type (ie, Medicare, private payer, Medicaid). Upon request, the *HYMOVIS® Support Hotline* will conduct benefit verifications that provide coverage and coding information that is specific to your patient's health insurance coverage. The *Hotline* program is available Monday through Friday from 9:00 AM to 8:00 PM ET at 1-866 HYMOVIS® (1-866-496-6847).



MEDICARE NATIONAL AVERAGE REIMBURSEMENT RATE INFORMATION*

| Site of Service CPT Code | | Website for Look-up | | |
|--------------------------|-------|--|--|--|
| Physician | 20610 | https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ | | |
| Office | 20611 | PFSlookup/index.html | | |
| Hospital | 20610 | https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ | | |
| Outpatient | 20611 | HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html | | |
| Ambulatory | 20610 | https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ | | |
| Surgical Center | 20611 | ASCPayment/11_Addenda_Updates.html | | |

^{*}Reimbursement rates for CPT codes vary by geography; consult the CMS website for regional rates applicable to the practice or contact the local Medicare Administrative Contractor for regional rates.



PRIOR AUTHORIZATION CHECKLIST

The HYMOVIS® Support Hotline is happy to assist you with obtaining information for prior authorization (PA) for HYMOVIS® (high molecular weight viscoelastic hyaluronan). However, if your office chooses to obtain this information without the assistance of the HYMOVIS® Support Hotline, please use the checklist below to ensure that you are obtaining the information you need from your patient's insurer.

| Patient Name: | | DOB: | | | |
|--|--|---------------------|----------------------|---|--|
| Payer Name: | Phone # | : | Date: | | |
| Overtions to Ask | | Δ = σ | | | |
| | | Ans | | | |
| Is a PA required? | ☐ Yes | | □ No | | |
| What information is needed by the insurer for the PA? | □ Diagnosis □ P □ Other: | revious therapy 🗆 C | Chart notes | | |
| Does the patient need to have a failure, contraindication, or intolerance to the following treatment options? | □ Intra-articular co □ Non-steroidal an | Yes | | | |
| Does the patient need to have documented symptomatic osteoarthritis of the knee? | □ Yes | | □ No | | |
| Door the nations need to have tried any | ☐ Yes (if yes, compl | lete below) | □No | | |
| Questions to Ask Is a PA required? What information is needed by the insurer for the PA? Does the patient need to have a failure, contraindication, or intolerance to the following treatment options? Does the patient need to have documente symptomatic osteoarthritis of the knee? Does the patient need to have tried any other medications for the condition? Does the insurer have a specific PA form? If the insurer has a specific PA form, how is that form obtained (obtain website, provided portal address, and/or fax number)? How is the PA submitted to the insurer? (obtain phone, fax, and/or portal address) Will the insurer provide a PA number to include on the claim form? How long does it take the insurer to review the PA request? Is there a required specialty pharmacy for HYMOVIS® acquisition? If a specialty pharmacy provides HYMOVIS®, who obtains the PA? | Medication/Therapy: | | Duration of Therapy: | | |
| Does the insurer have a specific PA form? | □ Yes | | □No | | |
| If the insurer has a specific PA form, how is | Online | Insurer provider po | rtal | Fax | |
| other medications for the condition? Does the insurer have a specific PA form? If the insurer has a specific PA form, how is hat form obtained (obtain website, provide portal address, and/or fax number)? How is the PA submitted to the insurer? | | | | | |
| | Phone | Insurer provider po | rtal | pht loss if overweight) profen) erapy: Fax Fax | |
| | | | | | |
| Will the insurer provide a PA number to | ☐ Yes | | □No | | |
| Is a PA required? What information is needed by the insurer for the PA? Does the patient need to have a failure, contraindication, or intolerance to the following treatment options? Does the patient need to have document symptomatic osteoarthritis of the knee? Does the patient need to have tried any other medications for the condition? Does the insurer have a specific PA form? If the insurer has a specific PA form, how is that form obtained (obtain website, provide portal address, and/or fax number)? How is the PA submitted to the insurer? (obtain phone, fax, and/or portal address) Will the insurer provide a PA number to include on the claim form? How long does it take the insurer to review the PA request? Is there a required specialty pharmacy for HYMOVIS® acquisition? If a specialty pharmacy provides HYMOVIS, who obtains the PA? | PA Number: | | | | |
| | | | | | |
| Is there a required specialty pharmacy for | ☐ Yes (if yes, compl | lete below) | □No | | |
| to review the PA request? Is there a required specialty pharmacy for HYMOVIS®acquisition? | Specialty pharmacy: | | | | |
| | □ Specialty pharmo | асу | ☐ Provider office | | |
| How long is the PA valid for HYMOVIS®? | | | | | |



NEED ASSISTANCE? Contact the HYMOVIS® Support Hotline.

Call 1-866-HYMOVIS (1-866-496-6847) between 9 AM and 8 PM ET, Monday through Friday.

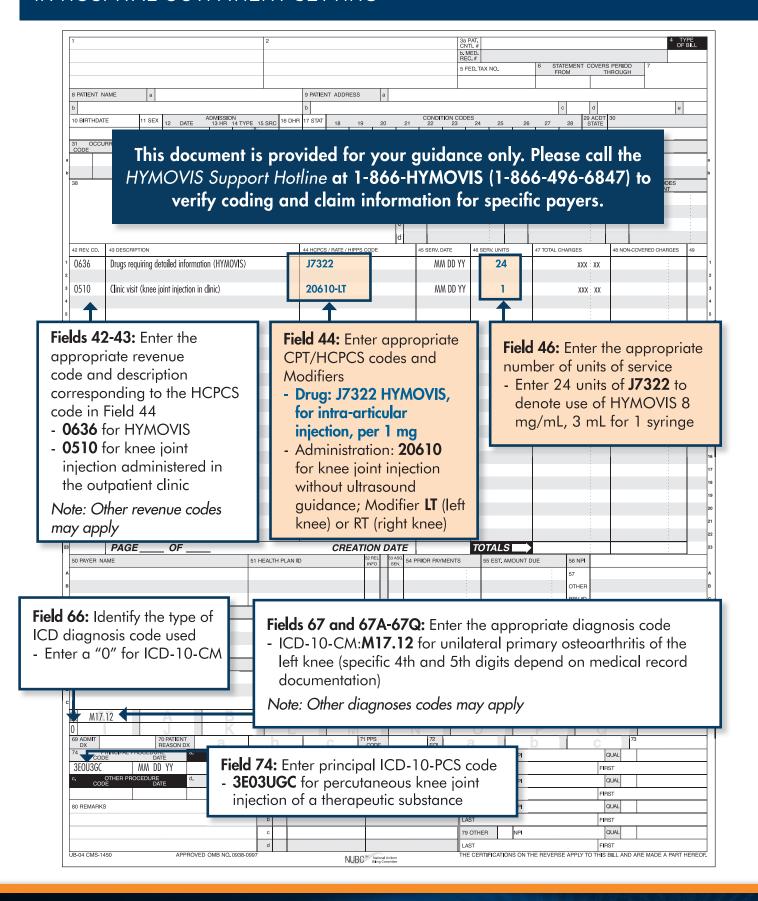


SAMPLE CMS-1500 CLAIM FORM FOR HYMOVIS® (HIGH MOLECULAR WEIGHT VISCOELASTIC HYALURONAN)

| HEALTH INSURANCE CLAIM FOR APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUC | | | | | CARRIER CARRIER | |
|--|--|-------------------------|--|--|--|---|
| (Medicare#) (Medicaid#) (ID#/DoD#) 2. PATIENT'S NAME (Last Name, First Name, Middle Initial) | CHAMPVA GROUP HEALTH PLAN BL (Member ID#) (ID#) (ID#) (ID MEMBER ID#) (ID MEMB | KLUNG (ID#) | 1a. INSURED'S I.D. NUMBEI 4. INSURED'S NAME (Last N | R (For Program in lame, First Name, Middle Initial) | n Item 1) | |
| HYMOVIS® Supp | provided for you ort Hotline at 1-86 ing and claim info | 66 ⁻ HYMC | OVIS (1-866- | -496-6847) | ode) NOLONG NOLO | |
| a. OTHER INSURED'S POLICY OR GROUP NUMBER b. RESERVED FOR NUCC USE | a. EMPLOYMENT? (Current or YES b. AUTO ACCIDENT? | NO | a. INSURED'S DATE OF BIR MM DD Y | Υ M | NSURED | |
| c. RESERVED FOR NUCC USE | c. OTHER ACCIDENT? | NO L | c. INSURANCE PLAN NAME | | ATIENT AND | |
| d. INSURANCE PLAN NAME OR PROGRAM NAME READ BACK OF FORM BEFORE COI 12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE Lauth | 10d. CLAIM CODES (Designate IPLETING & SIGNING THIS FORM. Portion the release of any medical or other infe | | | ALTH BENEFIT PLAN? If yes, complete items 9, 9a, and RIZED PERSON'S SIGNATURE I au its to the undersigned physician or s | d 9d. | |
| SIGNED 14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANG MM DD YY QUAL. | Box 21 ICD Indicator: ype of ICD diagnosis c enter a "0" for ICD-10 | ode used; | TENT UNABL DD | E TO WORK IN CURRENT OCCUP MM DD TO DD TO | PATION A | |
| 17. NAME OF REFERRING PROVIDER OR OTHER SOURGE 1 | -L to service line below (24E) C D. G H. | 0 | FROM DD DD PROMISE TO THE PROME DD | Box 23 Prior Au Enter the payer au number as obtaine services rendered | ıthorizatioı | n |
| I. | K. L. L. PROCEDURES, SERVICES, OR SUPPL | IES E. | F. G | | 1 | |
| From To PLACE OF | (Explain Unusual Circum stances) CPT/HCPCS ODIFIER J7322 20610-LT | DIAGNOSIS POINTER A A | \$ CHARGES XX XX 24 XX XX 1 | Box 24G Ur the appropria of units of ser J7322 is per syringe of HY is 24 units) | ate number vice (eg, 1 mg, for | а |
| Box 24D Procedures/Service | es/Supplies: | | | NPI | | |
| Enter the appropriate CPT/HCl and modifiers - J-code: J7322 for HYMOV - Administration: eg, 20610, a aspiration, and/or injection, or bursa, without ultrasound g - Modifier: eg, LT for left knee | IS, per mg rthrocentesis, major joint | code (eg osteoarth | g, ICD-10-CM: nritis, left knee) | er the appropriate M17.12, unilatera | l primary | |
| SIGNED DATE NUCC Instruction Manual available at: www.nucc. | NPI b. | | a. NP | b. OMB APPROVAL | L PENDING | |



SAMPLE CMS-1450 (UB-04) CLAIM FORM FOR HYMOVIS® (HIGH MOLECULAR WEIGHT VISCOELASTIC HYALURONAN) IN HOSPITAL OUTPATIENT SETTING





TIPS FOR CLEAN CLAIMS SUBMISSION

The most common reasons for denied claims include:

Use of incorrect codes on claim

Incorrect number of units reported

Omission of letter of medical necessity

Missing or incorrect information on claim form (eg, misspelled patient name)

Failure to obtain a PA before initiating treatment or failure to include the PA approval number on the claim form

Since payers may have different guidelines for coding and claims filing, it is important to check with individual plans to research claims-submission requirements.

Not all payers will be familiar with HYMOVIS® (high molecular weight viscoelastic hyaluronan) since it is a newer product and billed with its own unique HCPCS code. Payers may need more information about a product if they are unfamiliar with it and may request additional information about the patient's treatment or diagnosis in order to determine whether a treatment is medically necessary. A letter of medical necessity may help to explain why HYMOVIS® is medically necessary for the patient's treatment. Claims for HYMOVIS® may include supporting materials such as:



Customized letter of medical necessity



Package insert







Patient medical history





Prior therapies





Strategies to Appeal Denied Claims

If a claim for HYMOVIS® (high molecular weight viscoelastic hyaluronan) is improperly reimbursed or denied, you may consider submitting an appeal. The following list provides some tips for appealing denied claims:

Review the explanation of benefits (EOB) to determine the reason for the denial

If additional information is requested, submit the necessary documentation immediately

Submit a corrected claim if the denial was due to a technical billing error (eg, missing additional information associated with miscellaneous codes, incorrect patient identification number, missing diagnosis)

Verify the appeals process with the payer

- Is there a particular form that must be completed?
- Can the appeal be conducted over the phone or must it be in writing?
- To whom should the appeal be directed?
- What information must be included with the appeal (eg, copy of original claim, EOB, supporting documentation)?
- How long does the appeals process usually take?
- How will the payer communicate the appeal decision?

Review appeal request for accuracy, including patient identification numbers, coding, and requested information

Request that a specialist who is familiar with HYMOVIS® review the claim for medical necessity. It is preferable to have the claim reviewed by a specialist who is presently treating patients with HYMOVIS®

File claims appeal as soon as possible and within filing time limits

Reconcile claims appeal responses promptly and thoroughly to ensure appeals have been processed appropriately

Record appeals result (eg, payment amount or if further action is required)

If you have already submitted a letter of medical necessity, you should include a letter of appeal indicating why the product and/or the procedure should be covered and paid by the payer

Additionally, you should include a copy of the original claim and denial notification, the patient's complete medical history, the physician's plan for continuing treatment, and relevant journal articles supporting the use of HYMOVIS®

If this second claim submission is denied, it may be necessary to contact the payer's medical or claims director. Often a claim denial is reversed upon a director's review of an accurate and complete denial appeal request

For assistance in researching a payer's appeal process and preparing a denial appeal, please call the *HYMOVIS® Support Hotline* at 1-866-HYMOVIS® (1-866-496-6847). A reimbursement counselor can assist you in developing an appeal strategy. We will work with your practice or patient to assist in an appeal as most appropriate.

