CMS Implements The Appropriate Use Criteria Program

It has been estimated that improper Medicare payments cost taxpayers and beneficiaries about $50 billion a year. Congress and the Department of Health and Human Services have been taking steps to reduce the burden of wasteful spending in Medicare. As part of this effort, CMS has advanced the implementation of the Appropriate Use Criteria Program (required by the Protecting Access to Medicare Act of 2014) in the 2018 proposed Physician Fee Schedule (2018 PFS). While the current program applies to physicians ordering advanced diagnostic imaging services, the policy has significant implications for the future of clinical medicine.

In the first large-scale study to directly measure wasteful spending in Medicare, researchers in the Harvard Medical School Department of Health Care Policy estimated that Medicare spent $1.9 billion in 2009 for patients to receive any one of 26 tests and procedures that had been shown by empirical studies to offer little or no health benefit. Over the past decade, questions have been raised by the Institute of Medicine, recently renamed the National Academy of Medicine, the Office of Management and Budget, and the Harvard Medical School Department of Health Care Policy about the potential overuse of advanced diagnostic imaging services. In a 2008 report, the Office of Inspector General of the Department of Health and Human Services found that Medicare spending on advanced diagnostic imaging services more than doubled from 2000 through 2006, growing far faster than other imaging services. In response, Congress included a provision in the Protecting Access to Medicare Act of 2014, requiring any physician ordering a MRI, CT, PET or nuclear medicine imaging studies, in all outpatient settings, to document the use of an approved clinical practice guideline, now referred to as a “qualified clinical decision support mechanism” (qCDSM) prior to submitting the request. This policy has been designated The Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging. This provision was strongly supported by the radiology societies.
As far back as the 1990s, the American College of Radiology (ACR) felt a need to define national guidelines for appropriate use of imaging technologies. An ACR Task Force on Appropriateness Criteria was created in late 1993. In 1994, deliberations had begun to develop nationally accepted, scientifically-based guidelines to assist referring physicians in making appropriate imaging decisions for given patient clinical conditions. These guidelines became known as the ACR Appropriateness Criteria. In June 2016, the Centers for Medicare & Medicaid Services named the American College of Radiology a “qualified Provider-Led Entity” approved to provide appropriate use criteria (AUC) under the Medicare Appropriate Use Criteria program for advanced diagnostic imaging.

Qualified Provider-Led Entity

The Appropriate Use Program relies on readily accessible clinical practice guidelines, aka qCDSM, either embedded in the electronic medical record or available on an independent website. The development of the qCDSM requires a cooperative effort between a recognized medical society or physician organization and a Medicare certified software developer. Medical societies interested in participating must apply to CMS to become qualified. Qualified Provider Led Entities (PLEs) as of June 2017 include:

American College of Cardiology Foundation
American College of Radiology
Banner University Medical Group-Tucson University of Arizona
CDI Quality Institute
Cedars-Sinai Health System
Intermountain Healthcare
Massachusetts General Hospital, Department of Radiology
Medical Guidelines Institute
Memorial Sloan Kettering Cancer Center
National Comprehensive Cancer Network
Sage Evidence-based Medicine & Practice Institute*
Society for Nuclear Medicine and Molecular Imaging
University of California Medical Campuses
University of Utah Health
University of Washington School of Medicine
Virginia Mason Medical Center
Weill Cornell Medicine Physicians Organization

Medicare certified software developers as of June 2017 include:

Applied Pathways CURION™ Platform
Cranberry Peak ezCDS
eviCore healthcare's Clinical Decision Support Mechanism
National Decision Support Company CareSelect™*
nNational Imaging Associates RadMD
Sage Health Management Solutions Inc. RadWise®
Test Appropriate CDSM

Incorporating the AUC Program Into the Physicians Fee Schedule

In the 2017 Physician Fee Schedule final rule CMS published the first list of priority clinical areas representing about 40 percent of advanced diagnostic imaging services paid for by Medicare:

- Coronary artery disease (suspected or diagnosed).
Suspected pulmonary embolism.
- Headache (traumatic and non-traumatic).
- Hip pain.
- Low back pain.
- Shoulder pain (to include suspected rotator cuff injury).
- Cancer of the lung (primary or metastatic, suspected or diagnosed).
- Cervical or neck pain.

In the 2018 proposed Physician Fee Schedule (2018 PFS) CMS confirmed the requirement for the physician requesting an advanced imaging study to consult with a Qualified Clinical Decision Support Mechanism when ordering an advanced imaging service. That physician is then required to provide documentation to the radiology service regarding that action. The physician furnishing the service must include that information on the Medicare claim for payment. Beginning January 1, 2019, payment will only be made to the furnishing physician and facility if the claim for the service includes the required AUC documentation. The information required to be provided by the ordering physician and included on the claims for payment by both the furnishing physician and the outpatient facility includes:

1) Which qCDSM was consulted by the ordering provider;
2) Whether the service ordered would adhere to specified applicable AUC, would not adhere to specified applicable AUC, or whether specified applicable AUC were not applicable to the service ordered;
3) The National Provider Identifier of the ordering provider.

To implement this policy CMS has proposed to establish a series of HCPCS level 3 codes. These G-codes would describe the specific qCDSM that was used by the ordering physician. In addition, CMS will create a series of modifiers to be added to the G code to satisfy reporting on criteria 2. Each G-code submitted would be expected, on the same claim line, to contain at least one new HCPCS modifier. Codes will also be created to describe situations where an exception applies and a qualified qCDSM was not used. While the penalty for the facility that performs the study and the physician that supervises and interprets the study is financial, the physician that requests the study but does not consult the qCDSM and provide the appropriate G code and modifier will be designated an outlier by CMS and required to obtain preauthorization for all studies requested.

CMS has proposed to implement a one-time 6-month voluntary reporting period beginning sometime in 2018, as well as a mandatory annual reporting requirement beginning January 1, 2019. During this first year, CMS is proposing to pay claims for advanced diagnostic imaging services regardless of whether they contain information on the required AUC consultation. During the 6-month voluntary participation period, CMS estimates 3,410,000 responses in the form of consultations based on market
research. Beginning January 1, 2019, they anticipate 43,181,818 responses in the form of consultations based on Medicare claims data for advanced diagnostic imaging services.

Pulmonary Issues

In 2012, The Coverage and Analysis Group of CMS engaged the Federally Funded Research and Development Center (FFRDC) a division of the CMS Alliance to Modernize Healthcare to help establish priority clinical areas for the Medicare appropriate use criteria program. On May 20, 2016 this Research and Development Center issued an in depth report of findings from analyzing claims data from the Medicare population and their utilization of advanced imaging procedures for calendar year 2014. In that year, for all pulmonary symptoms and abnormal plain films 1,745,202 advanced diagnostic studies were billed to Medicare. For comparison, in the largest diagnostic category, heart condition, the total number of advanced radiologic studies, including sonography, for cardiac symptoms was 5,038,483 and for acute abdominal pain there were 2,303,761 studies.

In the summary of their study the FFRDC concluded that, for the most part, advanced imaging techniques were being correctly and appropriately applied according to the diagnosis codes and the corresponding imaging modalities used to investigate them. Without much evidence of abuse of diagnostic imaging for pulmonary related issues CMS has narrowed its focus to suspected pulmonary embolism and studies for lung cancer. As far as pulmonary embolism studies go there is an exception for studies ordered on an emergency basis. That means there is no requirement for the ordering physician to consult a Qualified Clinical Decision Support or report a G code on the request.

The Benefit of the Program

While estimates of wasteful spending in Medicare are as high as $50 billion a year, the Congressional Budget Office has estimated that the Appropriate Use Criteria for Advanced Diagnostic Imaging program would save approximately 200 million dollars over 10 years. In comparison, payments for prescription drugs and payments to home health agencies comprise the great majority of improper payments. Primary care physicians average 13 prescriptions per Medicare patient; however, the OIG has identified over 100 primary care physicians who have prescribed more than 70 medications per Medicare patient and one pharmacy that billed an average of 116 prescriptions per Medicare patient. The median number of visits per Medicare patient across all Medicare home health agencies has been 32 while 13 home health agencies billed for more than 300 visits per Medicare patient in one year. The OIG also found that errors and inefficiencies among the Medicare Administrative Contractors, including paying for the prescriptions and services noted above, was a significant contributor to waste in the system. OIG reviews of these contractors over the past decade have consistently identified problems such as those just noted as well as paying for services or supplies on behalf of deceased beneficiaries. The OIG criticized the Medicare administration for failure to use data to assess contractor performance and an inadequate response when contractors did not meet performance standards.

Despite the report from the Federally Funded Research and Development Center and the relatively low financial gain expected from the CBO report, CMS is forging ahead with this program. This is probably the first step toward introducing clinical decision support software into other areas of clinical practice and associate them with financial penalties for lack of compliance. Numerous groups, including provider-led entities, such as medical specialty societies and government or non-profit entities, have developed appropriate use criteria. Of the services identified in the Harvard report as being of questionable or low-value, provider-led entities have developed appropriate use criteria for more than half of them. Commercial insurers are almost certainly closely following the implementation of this program.
One of the more prominent decision support software companies selected by CMS for the diagnostic imaging program, The National Decision Support Company, has developed products that can provide administrators information on which physicians are ordering inappropriate studies frequently, which users are following the clinical decision support recommendations, and how many orders are changed because of decision support feedback. They have also developed programs that evaluate the use of commonly ordered laboratory tests based on guidelines from Choosing Wisely, blood utilization management and feedback pertaining to medication orders utilizing patient-specific information, pertinent laboratory results, and prescribed dosing regimens. So what does this mean for clinical practice in 2019 and beyond? An increasing documentation burden with increasing requirements to comply with evidence based guidelines that have been embedded in electronic health records by software companies as well as real time scrutiny of clinical activity by practice administrators, insurance companies and the Medicare administration.

**PRODUCT AND TECHNOLOGY NEWS!**

NAMDRC is providing this space to our benefactors and patrons who provide us with information about new products and innovations related to pulmonary medicine. NAMDRC reserves the right to edit this copy as appropriate.

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Genentech, a NAMDRC Industry Advisory Committee member, has submitted an Esbriet article. This article continues on the next three pages.
gastrointestinal events was required in 18.5% of patients in the
treated with Esbriet. Dosage reduction or interruption for
diarrhea, dyspepsia, vomiting, gastroesophageal reflux disease,
be necessary.

cause photosensitivity. Dosage reduction or discontinuation may
exposure. Patients should avoid concomitant medications that
minimize exposure to sunlight (including sunlamps), use a sunblock
had a higher incidence of photosensitivity reactions (9%) compared
then monthly for the first 6 months and every 3 months thereafter.
the combination of transaminase elevations and elevated bilirubin
of elevations in ALT or AST than placebo patients (3.7% vs 0.8%,
are nausea, rash, abdominal pain, upper respiratory tract infection,
were gastroesophageal reflux disease, sinusitis, insomnia, weight
dosage reductions are recommended. Monitor patients closely when
inhibitor of CYP1A2) moderately increases exposure to Esbriet. If
reductions of Esbriet are recommended. Monitor for adverse reactions
inhibitor of CYP1A2) cannot be avoided, dosage
reductions are recommended. Monitor patients closely when
of strong CYP1A2 inhibitors should be avoided.
the safety, efficacy, and pharmacokinetics of Esbriet have not been studied in patients with
changes in %FVC from baseline at 52 weeks. In CAPACITY 004, 348
subjects, with over 170 subjects exposed to pirfenidone for more
that led to dosage reduction or interruption were nausea, diarrhea, vomiting,
placibo group. 2.2% of patients in the Esbriet 2403 mg/day
the other hand, dosages reduced for diaphoresis may be necessary in some cases.
Adverse reactions: The most common adverse reactions (≥15%) are
nausea, rash, abdominal pain, upper respiratory tract infection,
diarrhea, fatigue, headache, dyspepsia, diarrhea, vomiting, anorexia,
gastrointestinal reflux disease, insulin, insomnia, weight decrease,
and photosensitivity. Drug interactions: Concurrent administration with strong
inhibitors of cytochrome P450 (CYP) isoenzymes involved in the metabolism of Esbriet
concurrent administration of Esbriet and rifampin (a moderate
inhibitor of CYP3A4) moderately increases exposure to Esbriet. If
concurrent administration of rifampin (a moderate inhibitor of CYP3A4) moderately increases exposure to Esbriet. If
Concomitant administration of Esbriet and rifampin (a moderate
inhibitor of CYP3A4) should be avoided.
Gastrointestinal disorders: Gastrointestinal events of nausea, diarrhea,
dyspepsia, vomiting, gastrointestinal reflux disease, abdominal pain were more frequently reported in patients
treated with Esbriet. Dissease reduction or interruption for
gastrointestinal events was required in 18.7% of patients in the
placibo group. 2.2% of patients in the Esbriet 2403 mg/day
group discontinued treatment due to a gastrointestinal event, as
compared to 1.5% in the placibo group. The most common (≥15%)
gastrointestinal events that led to dosage reduction or interruption were nausea, diarrhea, vomiting,
dyspepsia, abdominal pain, upper respiratory tract infection, stool
frequency, rash, headache, dyspepsia, diarrhea, vomiting, anorexia,
gastroesophageal reflux disease, insomnia, insomnia, weight decrease,
and photosensitivity...
5.2 Photosensitivity Reaction or Rash

Patients treated with ESBRIET 2403 mg/day in the three Phase 3 studies had a higher incidence of photosensitivity reactions (9%) compared with patients treated with placebo (1%). The majority of the photosensitivity reactions occurred during the initial 6 months. Instruct patients to avoid sunlight (including sunlamps), to use a sunblock (SPF 50 or higher), and to wear clothing that protects against sun exposure. Additionally, instruct patients to avoid sunlight (including sunlamps), to use a sunblock (SPF 50 or higher), and to wear clothing that protects against sun exposure. If photosensitivity reactions leading to dosage reduction or interruption were rash and nausea. The most common (>10%) adverse reactions leading to dosage reduction or interruption were rash, nausea, diarrhea, and photosensitivity reaction.

The most common adverse reactions with an incidence of ≥10% and more frequent in the ESBRIET than placebo treatment group are listed in Table 2.

Table 2. Adverse Reactions Occurring in ≥10% of ESBRIET-Treated Patients and More Commonly Than Placebo in Studies 1, 2, and 3

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>ESBRIET 2403 mg/day (N = 623)</th>
<th>Placebo (N = 624)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>36%</td>
<td>16%</td>
</tr>
<tr>
<td>Rash</td>
<td>30%</td>
<td>10%</td>
</tr>
<tr>
<td>Abdominal Pain1</td>
<td>24%</td>
<td>15%</td>
</tr>
<tr>
<td>Upper Respiratory Tract Infection</td>
<td>27%</td>
<td>25%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>26%</td>
<td>20%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>26%</td>
<td>19%</td>
</tr>
<tr>
<td>Headache</td>
<td>22%</td>
<td>19%</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>19%</td>
<td>7%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>18%</td>
<td>11%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>13%</td>
<td>6%</td>
</tr>
<tr>
<td>Anorexia</td>
<td>13%</td>
<td>5%</td>
</tr>
<tr>
<td>Gastro-esophageal Reflux Disease</td>
<td>11%</td>
<td>7%</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>11%</td>
<td>10%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>10%</td>
<td>7%</td>
</tr>
<tr>
<td>Weight Decreased</td>
<td>10%</td>
<td>5%</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>10%</td>
<td>7%</td>
</tr>
</tbody>
</table>

1 Includes abdominal pain, upper abdominal pain, abdominal distension, and stomach discomfort.

Adverse reactions occurring in ≥5 to <10% of ESBRIET-treated patients and more commonly than placebo are photosensitivity reaction (9% vs. 1%), decreased appetite (8% vs. 3%), pruritus (8% vs. 5%), asthenia (6% vs. 4%), dysgeusia (6% vs. 2%), and non-cardiac chest pain (5% vs. 4%).

6.2 Postmarketing Experience

In addition to adverse reactions identified from clinical trials the following adverse reactions have been identified during post-approval use of pirfenidone. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency.

Blood and Lymphatic System Disorders
Agranulocytosis
Immune System Disorders
Angioedema
Hepatobiliary Disorders
Bilirubin increased in combination with increases of ALT and AST

7 DRUG INTERACTIONS

7.1 CYP1A2 Inhibitors

Pirfenidone is metabolized primarily (70 to 80%) via CYP1A2 with minor contributions from other CYP isoenzymes including CYP2C9, 2C19, 2D6 and 2E1.

Strong CYP1A2 Inhibitors

The concomitant administration of ESBRIET and fluvoxamine or other strong CYP1A2 inhibitors (e.g., enoxacin) is not recommended because it significantly increases exposure to ESBRIET [see Clinical Pharmacology section 7.3 in full Prescribing Information]. Use of fluvoxamine or other strong CYP1A2 inhibitors should be discontinued prior to administration of ESBRIET and avoided during
ESBRIET® (pirfenidone)

**ESBRIET** treatment. In the event that fluvoxamine or other strong CYP1A2 inhibitors are the only drug of choice, dosage reductions are recommended. Monitor for adverse reactions and consider discontinuation of ESBRIET as needed [see Dosage and Administration section 2.4 in full Prescribing Information].

**Moderate CYP1A2 Inhibitors**

Concomitant administration of ESBRIET and ciprofloxacin (a moderate inhibitor of CYP1A2) moderately increases exposure to ESBRIET [see Clinical Pharmacology section 12.3 in full Prescribing Information]. If ciprofloxacin at the dosage of 750 mg twice daily cannot be avoided, dosage reductions are recommended [see Dosage and Administration section 2.4 in full Prescribing Information]. Monitor patients closely when ciprofloxacin is used at a dosage of 250 mg or 500 mg once daily.

Concomitant CYP1A2 and other CYP Inhibitors

Agents or combinations of agents that are moderate or strong inhibitors of both CYP1A2 and one or more other CYP isoenzymes involved in the metabolism of ESBRIET (i.e., CYP2C9, 2C19, 2D6, and 2E1) should be discontinued prior to and avoided during ESBRIET treatment.

7.2 CYP1A2 Inducers

The concomitant use of ESBRIET and a CYP1A2 inducer may decrease the exposure of ESBRIET and this may lead to loss of efficacy. Therefore, discontinue use of strong CYP1A2 inducers prior to ESBRIET treatment and avoid the concomitant use of ESBRIET and a strong CYP1A2 inducer [see Clinical Pharmacology section 12.3 in full Prescribing Information].

**8 USE IN SPECIFIC POPULATIONS**

8.1 Pregnancy

**Risk Summary**

The data with ESBRIET use in pregnant women are insufficient to inform on drug associated risks for major birth defects and miscarriage. In animal reproduction studies, pirfenidone was not teratogenic in rats and rabbits at oral doses up to 3 and 2 times, respectively, the maximum recommended daily dose (MRDD) [see Data].

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2–4% and 15–20%, respectively.

**Data**

**Animal Data**

Animal reproductive studies were conducted in rats and rabbits. In a combined fertility and embryofetal development study, female rats received pirfenidone at oral doses of 0, 50, 150, 450, and 1000 mg/kg/day from 2 weeks prior to mating, during the mating phase, and throughout the periods of early embryonic development from gestation days (GD) 0 to 5 and organogenesis from GD 6 to 17. In an embryofetal development study, pregnant rabbits received pirfenidone at oral doses of 0, 30, 100, and 300 mg/kg/day throughout the period of organogenesis from GD 6 to 18. In these studies, pirfenidone at doses up to 3 and 2 times, respectively, the maximum recommended daily dose (MRDD) in adults (see Data). In rats and rabbits, respectively, revealed no evidence of impaired fertility or harm to the fetus due to pirfenidone. In the presence of maternal toxicity, acyclic/irregular cycles (e.g., prolonged estrous cycle) were seen in rats at doses approximately equal to and higher than the MRDD in adults (on a mg/m² basis at maternal doses of 450 mg/kg/day and higher). In a pre- and post-natal development study, female rats received pirfenidone at oral doses of 0, 100, 300, and 1000 mg/kg/day from GD 7 to lactation day 20. Prolongation of the gestation period, decreased numbers of live newborn, and reduced pup viability and body weights were seen in rats at an oral dosage approximately 3 times the MRDD in adults (on a mg/m² basis at a maternal oral dose of 1000 mg/kg/day).

8.2 Lactation

**Risk Summary**

No information is available on the presence of pirfenidone in human milk, the effects of pirfenidone or its metabolites are excreted in milk. There are no data on the presence of pirfenidone or its metabolites in human milk, the effects of pirfenidone on the breastfed child, or its effects on milk production.

**Data**

**Animal Data**

A study with radio-labeled pirfenidone in rats has shown that pirfenidone or its metabolites are excreted in milk. There are no data on the presence of pirfenidone or its metabolites in human milk, the effects of pirfenidone on the breastfed child, or its effects on milk production.

8.4 Pediatric Use

Safety and effectiveness of ESBRIET in pediatric patients have not been established.

8.5 Geriatric Use

Of the total number of subjects in the clinical studies receiving ESBRIET, 714 (67%) were 65 years old and over, while 231 (22%) were 75 years old and over. No overall differences in safety or effectiveness were observed between older and younger patients. No dosage adjustment is required based upon age.

8.6 Hepatic Impairment

ESBRIET should be used with caution in patients with mild (Child Pugh Class A) to moderate (Child Pugh Class B) hepatic impairment. Monitor for adverse reactions and consider dosage modification or discontinuation of ESBRIET as needed [see Dosage and Administration section 2.3 in full Prescribing Information].

The safety, efficacy, and pharmacokinetics of ESBRIET have not been studied in patients with severe hepatic impairment. ESBRIET is not recommended for use in patients with severe (Child Pugh Class C) hepatic impairment [see Clinical Pharmacology section 12.3 in full Prescribing Information].

8.7 Renal Impairment

ESBRIET should be used with caution in patients with mild (CLcr, 50–80 mL/min), moderate (CLcr, 30–50 mL/min), or severe (CLcr, less than 30 mL/min) renal impairment [see Clinical Pharmacology section 12.3 in full Prescribing Information]. Monitor for adverse reactions and consider dosage modification or discontinuation of ESBRIET as needed [see Dosage and Administration section 2.3 in full Prescribing Information]. No information is available on the presence of pirfenidone in human milk, the effects of pirfenidone on the breastfed child, or from the underlying maternal condition. Determination of the risk of ESBRIET to an infant during lactation; therefore, the potential adverse effects of the underlying maternal condition. Development and health benefits of breastfeeding should be considered along with the mother's clinical need for ESBRIET and the potential adverse effects on the breastfed child from ESBRIET or from the underlying maternal condition.

8.8 Smokers

Smoking causes decreased exposure to ESBRIET [see Clinical Pharmacology section 12.3 in full Prescribing Information], which may alter the efficacy profile of ESBRIET. Instruct patients to stop smoking prior to treatment with ESBRIET and to avoid smoking when using ESBRIET.

10 OVERDOSAGE

There is limited clinical experience with overdose. Multiple doses of ESBRIET up to a maximum tolerated dose of 4005 mg per day were administered as five 267 mg capsules three times daily to healthy adult volunteers over a 12-day dose escalation. In the event of a suspected overdose, appropriate supportive medical care should be provided, including monitoring of vital signs and observation of the clinical status of the patient.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

**Liver Enzyme Elevations**

Advise patients that they may be required to undergo liver function testing periodically. Instruct patients to immediately report any symptoms of a liver problem (e.g., skin or the white of eyes turn yellow, urine turns dark or brown [tea colored], pain on the right side of stomach, bleed or bruise more easily than normal, lethargy) [see Warnings and Precautions (5.1)].

**Photosensitivity Reaction or Rash**

Advise patients to avoid or minimize exposure to sunlight (including sunlamps) during use of ESBRIET because of concern for photosensitivity reactions or rash. Instruct patients to use a sunblock and to wear clothing that protects against sun exposure. Instruct patients to report symptoms of photosensitivity reaction or rash to their physician. Temporary dosage reductions or discontinuations may be required [see Warnings and Precautions (5.2)].

**Gastrointestinal Events**

Instruct patients to report symptoms of persistent gastrointestinal effects including nausea, diarrhea, dyspepsia, vomiting, gastro-esophageal reflux disease, and abdominal pain. Temporary dosage reductions or discontinuations may be required [see Warnings and Precautions (5.3)].

**Smokers**

Encourage patients to stop smoking prior to treatment with ESBRIET and to avoid smoking when using ESBRIET.

11 TREATMENT WITH EXCERPTED MATERIALS

11.1 Invasive Procedures

Advise patients to temporary dosage reductions or discontinuations may be required [see Warnings and Precautions (5.2)].

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Liver Enzyme Elevations

Advise patients that they may be required to undergo liver function testing periodically. Instruct patients to immediately report any symptoms of a liver problem (e.g., skin or the white of eyes turn yellow, urine turns dark or brown [tea colored], pain on the right side of stomach, bleed or bruise more easily than normal, lethargy) [see Warnings and Precautions (5.1)].

Photosensitivity Reaction or Rash

Advise patients to avoid or minimize exposure to sunlight (including sunlamps) during use of ESBRIET because of concern for photosensitivity reactions or rash. Instruct patients to use a sunblock and to wear clothing that protects against sun exposure. Instruct patients to report symptoms of photosensitivity reaction or rash to their physician. Temporary dosage reductions or discontinuations may be required [see Warnings and Precautions (5.2)].

Gastrointestinal Events

Instruct patients to report symptoms of persistent gastrointestinal effects including nausea, diarrhea, dyspepsia, vomiting, gastro-esophageal reflux disease, and abdominal pain. Temporary dosage reductions or discontinuations may be required [see Warnings and Precautions (5.3)].

Smokers

Encourage patients to stop smoking prior to treatment with ESBRIET and to avoid smoking when using ESBRIET.

Take with Food

Instruct patients to take ESBRIET with food to help decrease nausea and dizziness.

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- Monthly publication of the Washington Watchline, providing timely information for practicing physicians;
- Publication of Current Controversies focusing on one specific Pulmonary/Critical Care Issue in each publication;
- Regulatory updates;
- Discounted Annual Meeting registration fees;
- The Executive Office Staff as a resource on a wide range of clinical and management issues; and
- The knowledge that NAMDRC is an advocate for you and your profession.

https://www.namdrc.org/content/issue-advocacy

One of NAMDRC’s primary reasons for existence is to provide both clinicians and patients with the most up-to-date information regarding pulmonary medicine. Bookmark this page!

The complexity of our nation’s health care system in general, and Medicare in particular, create a true challenge for physicians and their office staffs. One of NAMDRC’s key strengths is to offer assistance on a myriad of coding, coverage and payment issues.

In fact, NAMDRC members indicate that their #1 reason for belonging to and continuing membership in the Association is its voice before regulatory agencies and legislators. That effective voice is translated into providing members with timely information, identifying important Federal Register announcements, pertinent statements and notices by the Centers for Medicare and Medicaid Services, the Durable Medical Equipment Regional Carriers, and local medical review policies.

ABOUT NAMDRC:

Established over three decades ago, the National Association for Medical Direction of Respiratory Care (NAMDRC) is a national organization of physicians whose mission is to educate its members and address regulatory, legislative and payment issues that relate to the delivery of healthcare to patients with respiratory disorders.

NAMDRC members, all physicians, work in close to 2,000 hospitals nationwide, primarily in respiratory care departments and critical/intensive care units. They also have responsibilities for sleep labs, management of blood gas laboratories, pulmonary rehabilitation services, and other respiratory related services.
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2. Mail this application to:
   NAMDRC
   8618 Westwood Center Drive, Suite 210
   Vienna, VA  22182-2273

Please print clearly or type:

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Individual and Small Group Dues…......$370.00
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(For larger groups, please attach a list of names. If a group member wishes to receive mailings at an address other than that indicated above, please attach appropriate information.)

Groups of 7-10……………………………..$1,175.00
Groups of 11-20……………………………..$1,560.00
Groups of 21-30……………………………..$1,930.00

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EXPIRATION DATE       SECURITY CODE

NAME AS IT APPEARS ON CREDIT CARD

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