The 2018 Medicare Hospital Inpatient Prospective Payment System

On August 14, 2017 the Centers for Medicare & Medicaid Services (CMS) published the final rule to update the 2018 Medicare Inpatient Prospective Payment System (IPPS) payment policies and rates for inpatient hospital care. This document, together with a proposal published on August 17, 2017, reflects the Medicare policy of the new administration within the existing legislated parameters.

The regulations governing Medicare reimbursement for hospital services have become increasingly complex in recent years. The 2018 IPPS affects 3,292 acute care hospitals representing approximately 55 percent of all Medicare-participating hospitals. While current regulations require a base update of 2.7 percent to hospital compensation, several recent legislative actions introduced adjustments, primarily negative, that affect the actual compensation a hospital will receive. These adjustments include a multifactor productivity adjustment and a 2018 adjustment required under the Affordable Care Act. These factors reduce the base update to hospital compensation to an increase of 1.35 percent.

For many hospitals payments for patient services will be reduced by penalties assessed under the various quality improvement programs. These programs include the Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate (RSRR), the Hospital Acquired Condition Reduction Program (HAC) and the Hospital Value-Based Purchasing (VBP) Program. CMS has estimated that 2,591 hospitals will have their base operating DRG payments reduced by their hospital-specific readmission adjustment. Based on their experience with the Hospital VBP program, CMS predicts that urban hospitals of more than 200 beds will experience a reduction in their base operating DRG payments. Under the HAC program they estimate that 23.2 percent of the 815 teaching hospitals with fewer than 100 residents, and 41.4 percent of the 249 teaching hospitals with 100 or more residents would be subject to a payment reduction. While these penalties pertain to compensation for Part A Medicare services, CMS has made it clear, on
several occasions, that they believe hospital administration has the ability to avoid financial penalties by influencing physician practice within their institution. With a significant amount of money on the line, physicians with inpatient practices, and particularly those in academic centers, will be under intense scrutiny by the hospital leadership.

2018 Inpatient Quality Reporting Program

CMS has finalized the existing 62 measures for the 2018 payment determination. The IQR metrics most applicable to pulmonary and critical care practices were listed in the May, 2017 Watchline.

2018 Hospital Value Based Purchasing Program

CMS has finalized the addition of the “Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode of Care for Pneumonia” measure beginning with the October 1, 2021 program year. This pneumonia payment measure would be added to the Efficiency and Cost Reduction domain of the Hospital Value Based Purchasing Program. The cohort for the PN Payment measure includes Medicare fee for service patients aged 65 or older with a principal hospital discharge diagnosis of pneumonia, including not only viral or bacterial pneumonia but also aspiration pneumonia or a principal discharge diagnosis of sepsis with a secondary diagnosis of pneumonia coded as present on admission.

The measure calculates payments for these patients over a 30-day episode-of-care, beginning with the index admission using administrative claims data. In order to construct the 30 day measures, CMS will establish a national baseline by collecting hospital data for a one year period. After a year of organizing and analyzing the data they repeat the data collection to determine an individual hospital’s performance relative to the baseline. Hospital compensation is then adjusted based on that data. For the pneumonia payment measure the data collection would be: baseline January 1, 2018 –December 31, 2018 and performance January 1, 2020–December 31, 2020.

Based on those results a payment adjustment would occur in Fiscal Year 2022. The pneumonia payment measure is intended to be paired with the Pneumonia 30 Day Mortality Measure in the Hospital VBP Program in an effort to link payment to quality.

The Hospital 30-day Risk-Standardized Readmission Rate

Over the past several years, a substantial amount of literature has recognized the impact of social risk factors on patient outcomes. Most outcome measures in the quality performance category and cost measures are affected by sociodemographic status, factors which are beyond the control of the provider. Academic medical centers tend to disproportionately treat disadvantaged and vulnerable patient populations and therefore are more likely to be unfairly penalized by performance programs that do not have adequate social risk factors adjustment. Reports from the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation and the National Academy of Medicine provide evidence that hospitals caring for large numbers of disadvantaged patients are more likely to receive penalties in the performance programs.

For many years the American Association of Medical Colleges (AAMC), and others, have tried to persuade CMS that including social risk factors in the risk adjustment of the readmission rate is important. In the proposed 2018 IPPS, CMS discussed the potential impact of social risk factors in the value-based purchasing and quality reporting programs and requested comments on how to account for them in its risk adjustment. In the finalized 2018 IPPS CMS states its intent to use “dual eligible” status, that is, a patient eligible for both Medicare and Medicaid, as a marker of
poverty among the patients included in the Pneumonia Readmission measure and the Pneumonia Mortality measure. This disparities indicator would provide information assessing the increased odds, or rates, of readmission for dual eligible patients admitted to the same hospital, after accounting for differences in age and comorbidities.

Hospital Acquired Conditions and Ventilator Associated Events

Since the inception of the Hospital Acquired Conditions program in 2007, CMS has tried to find a way to include ventilator associated pneumonia (VAP) or ventilator associated events (VAE) in the list of never events. The issue is raised on an annual basis in the proposed IPPS and each year CMS receives comments opposing the addition of VAE measures usually noting a lack of data on VAEs’ responsiveness to quality improvement initiatives. Most commenters have recommended delaying the adoption of such measures until more interventional studies are available to bolster the evidence base and better inform healthcare providers how best to reduce VAEs. Based on the general opposition, CMS has again deferred action on this issue for acute care hospitals but they are moving forward with quality measures for Long Term Care Hospitals (LTCH). Two measures are being implemented for patients on ventilators. These are Compliance with Spontaneous Breathing Trial by Day 2 of the Hospital Stay and the Ventilator Liberation Rate. Depending on their experience with these measures in LTCH, CMS may migrate similar metrics into the quality measures for acute care hospitals.

CMS Increases Focus on Measures of Behavioral Health

There are currently no measures of behavioral health in the Hospital IQR Program. In the proposed 2018 IPPS, CMS solicited feedback on the potential inclusion of measures to assess opioid prescribing practices, malnutrition, tobacco use, and substance use among the adult, inpatient population. A high priority are measures related to interventions on tobacco and opioid use. Smoking-attributable health care expenditures are estimated to cost at least $130 billion per year in direct medical expenses for adults and over $150 billion in lost productivity. Excessive alcohol consumption and drug misuse or abuse also have a significant impact on the health of the U.S. population. Excessive alcohol consumption is a leading cause of preventable death and disability resulting in approximately 88,000 deaths per year with an estimated economic cost of $249 billion, including $28 billion in direct health care costs.

CMS has been investigating the use of behavioral health related measures abstracted from the hospitals electronic medical record. These measures have been designated Electronic Clinical Quality Measures (eCQMs) and sets have been developed for tobacco
use and opiod addiction. The Joint Commission examined electronically abstracted tobacco and substance abuse measures from July 2015 to June 2016 and found that while there was good compliance and documentation of the tobacco use and substance use measures, there appeared to be little follow up with intervention.

### Tobacco Use Measures Screening Results July 2015-June 2016

<table>
<thead>
<tr>
<th>Measure Name</th>
<th>Screening Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tobacco Use Treatment Provided or Offered (TOB-2)</td>
<td>66.41%</td>
</tr>
<tr>
<td>Tobacco Use Treatment (TOB-2a)</td>
<td>32.97%</td>
</tr>
<tr>
<td>Tobacco Use Treatment Provided or Offered at Discharge (TOB-3)</td>
<td>46.20%</td>
</tr>
<tr>
<td>Tobacco Use Treatment at Discharge (TOB-3a)</td>
<td>10.71%</td>
</tr>
</tbody>
</table>

After reviewing the comments received CMS is taking no action this year but will probably add these measures to the hospital inpatient quality reporting requirement and the electronic health record program in the near future.

### Cancellation of the Episode Payment and Cardiac Rehabilitation Incentive Payment Models

In a significant reversal of previous policy, CMS Administrator Seema Verma issued a separate document on August 17, 2017 that proposed to cancel the Episode Payment Models (EPMs) and Cardiac Rehabilitation (CR) incentive payment model, due to be implemented in 2018, and to rescind the regulations governing these models. In this document Administrator Verma and Secretary of Health and Human Services Tom Price, MD, made it clear that review and reevaluation of policies and programs, as well as revised rulemaking, are within an agency’s discretion, and that discretion is often exercised after a change in administration occurs.

### Substance Use Measures Screening Results July 2015-June 2016

<table>
<thead>
<tr>
<th>Measure Name</th>
<th>Screening Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol Use Screening (SUB-1)</td>
<td>85.30%</td>
</tr>
<tr>
<td>Alcohol Use Brief Intervention Provided or Offered (SUB-2)</td>
<td>62.68%</td>
</tr>
<tr>
<td>Alcohol Use Brief Intervention (SUB-2a)</td>
<td>57.43%</td>
</tr>
<tr>
<td>Alcohol &amp; Other Drug Use Disorder Treatment Provided or Offered at Discharge (SUB-3)</td>
<td>65.46%</td>
</tr>
<tr>
<td>Alcohol &amp; Other Drug Use Disorder Treatment at Discharge (SUB-3a)</td>
<td>54.27%</td>
</tr>
</tbody>
</table>

We have noted Secretary Tom Price’s skepticism regarding the effectiveness of bundled payments and episode based models in the past. A primary factor in the current policy shift is the mandatory nature of these programs and the short time period allowed for hospitals and physicians to adapt. While not entirely discarding the possible future use of these payment models, they did indicate that any implementation would be on a voluntary basis. In view of this change in a pet project of the Center for Medicare and Medicaid Innovation, we anticipate that Secretary Price and Administrator Verma will either delay or abolish the requirement for physicians to add a responsibility code to each claim for services submitted on or after January 1, 2018. We look forward to the release of the Final version of the 2018 Medicare Physician Fee Schedule for more information.
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.

Genentech, a NAMDRC Industry Advisory Committee member, has submitted an Esbriet article entitled “We won’t back down from IPF. Help preserve more lung function. Reduce lung function decline.” This article continues on the next three pages.
Gastrointestinal events of nausea, vomiting, abdominal pain, dyspepsia, diarrhea, fatigue, anorexia, upper respiratory tract infection, and sinusitis were more frequent in patients treated with Esbriet than placebo. These events led to dosage reduction or interruption in 18.5% of patients. Dosage reduction or interruption for diarrhea, dyspepsia, vomiting, gastroesophageal reflux disease, sinusitis, insomnia, weight decrease, and anemia may be necessary in some cases.

Adverse reactions: The most common adverse reactions (≥15%) were nausea, rash, abdominal pain, upper respiratory tract infection, diarrhea, fatigue, headache, dyspepsia, dizziness, vomiting, anorexia, gastrointestinal reflux disease, insomnia, insomnia, weight decrease, and anemia.

Drug interactions: Concurrent administration with strong inhibitors of CYP1A2 (eg, ketoconazole) significantly increases systemic exposure of Esbriet and is not recommended. Discontinue prior to administration of Esbriet. If strong CYP1A2 inhibitors cannot be avoided, dosage reductions of Esbriet are recommended. Monitor for adverse reactions and consider discontinuation of Esbriet as needed.

Concomitant administration of Esbriet and ciprofloxacin (a moderate inhibitor of CYP1A2) moderately increases exposure to Esbriet. If ciprofloxacin is used at the dosage of 750 mg twice daily cannot be avoided, dosage reductions of Esbriet are recommended. Monitor patients closely when ciprofloxacin is used.

Agents that are moderate or strong inhibitors of both CYP1A2 and CYP3A4 (eg, fluvoxamine) significantly increase systemic exposure of Esbriet and is not recommended. Discontinue prior to administration of Esbriet. If strong CYP1A2 inhibitors cannot be avoided, dosage reductions of Esbriet are recommended. Monitor patients closely when ciprofloxacin is used.

Phototoxicity: Photosensitivity reaction or rash: Dosage modifications or interruption may be necessary.

Gastrointestinal disorders: Gastrointestinal events of nausea, diarrhea, dyspepsia, vomiting, gastrointestinal reflux disease, abdominal pain were more frequently reported in patients treated with Esbriet. Discharge reduction or interruption for gastrointestinal events was required in 28.5% of patients in the 2403 mg/day group, as compared to 5.8% of patients in the placebo 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 placebo group. The most common (>5%) gastrointestinal events that led to dosage reduction or interruption were nausea, diarrhea, vomiting, and dyspepsia. Discharge discontinuation may be necessary in some cases.

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**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 liver enzyme elevations

5 WARNINGS AND PRECAUTIONS

5.1 Elevated Liver Enzymes

Increases in ALT and AST >3 × ULN have been reported in patients treated with ESBRIET. In some cases these have been associated with concomitant elevations in bilirubin. Patients treated with ESBRIET 2403 mg/day in the three Phase 3 trials had a higher incidence of elevations in ALT or AST >3 × ULN than placebo patients (3.7% vs. 0.8%, respectively). Elevations >10 × ULN in ALT or AST occurred in 0.3% of patients in the ESBRIET 2403 mg/day group and in 0.2% of patients in the placebo group. Increases in ALT and AST >3 × ULN were reversible with dose modification or treatment discontinuation. No cases of liver transplant or death due to liver failure that were related to ESBRIET have been reported. However, the combination of transaminase elevations and elevated bilirubin without evidence of obstruction is generally recognized as an important predictor of severe liver injury, that could lead to death or the need for liver transplants in some patients. Conduct liver function tests (ALT, AST, and bilirubin) prior to the initiation of therapy with ESBRIET in all patients, then monthly for the first 6 months and every 3 months thereafter. Dosage modifications or interruption may be necessary for liver enzyme elevations [see Dosage and Administration section 2.1 and 2.3 in full Prescribing Information].

5.3 Gastrointestinal Disorders

In the clinical studies, gastrointestinal events of nausea, diarrhea, dyspepsia, vomiting, gastro-esophageal reflux disease, and abdominal pain were more frequently reported by patients in the ESBRIET treatment groups than in those taking placebo. Dosage reduction or interruption for gastrointestinal events was required in 18.5% of patients in the 2403 mg/day group, as compared to 5.8% of patients in the placebo group; 2.2% of patients in the ESBRIET 2403 mg/day group discontinued treatment due to a gastrointestinal event, as compared to 1.0% in the placebo group. The most common (>2%) gastrointestinal events that occurred more frequently in patients treated with ESBRIET than placebo are photosensitivity reaction (9% vs. 1%), decreased appetite (8% vs. 3%), pruritus (8% vs. 5%), abdominal pain (6% vs. 4%), dysgeusia (6% vs. 2%), and non-cardiac chest pain (5% vs. 4%).

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- **Liver Enzyme Elevations** [see Warnings and Precautions (5.1)]
- **Photosensitivity Reaction or Rash** [see Warnings and Precautions (5.2)]
- **Gastrointestinal Disorders** [see Warnings and Precautions (5.3)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The safety of pirfenidone has been evaluated in more than 1400 subjects with idiopathic pulmonary fibrosis (IPF).

ESBRIET® (pirfenidone)

(Studies 1, 2, and 3) in which a total of 623 patients received 2403 mg/day of ESBRIET and 624 patients received placebo. Subjects ages ranged from 40 to 80 years (mean age of 67 years). Most patients were male (74%) and Caucasian (95%). The mean duration of exposure to ESBRIET was 62 weeks (range: 2 to 118 weeks) in these 3 trials.

At the recommended dosage of 2403 mg/day, 14.6% of patients on ESBRIET compared to 9.8% on placebo permanently discontinued treatment because of an adverse event. The most common (>1%) adverse reactions leading to discontinuation were rash and nausea. The most frequent (1-3%) 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>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>% of Patients (0 to 118 Weeks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>ESBRIET 36% vs 16% Placebo</td>
</tr>
<tr>
<td>Rash</td>
<td>30% vs 10%</td>
</tr>
<tr>
<td>Abdominal Pain</td>
<td>24% vs 15%</td>
</tr>
<tr>
<td>Upper Respiratory Tract Infection</td>
<td>27% vs 25%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>26% vs 20%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>26% vs 19%</td>
</tr>
<tr>
<td>Headache</td>
<td>22% vs 19%</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>19% vs 7%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>18% vs 11%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>13% vs 6%</td>
</tr>
<tr>
<td>Anorexia</td>
<td>13% vs 5%</td>
</tr>
<tr>
<td>Gastro-esophageal Reflux Disease</td>
<td>11% vs 7%</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>11% vs 10%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>10% vs 7%</td>
</tr>
<tr>
<td>Weight Decreased</td>
<td>10% vs 5%</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>10% vs 7%</td>
</tr>
</tbody>
</table>

| 7 DRUG INTERACTIONS |

7.1 CYP1A2 Inhibitors

Pirfenidone is metabolized primarily (70 to 80%) via CYP1A2 with minor contributions from other CYP isoforms including CYP2C9, 2C19, 2D6, 2E1, and 2F1. 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 12.3 in full Prescribing Information]. Use of fluvoxamine or other strong CYP1A2 inhibitors should be discontinued prior to administration of ESBRIET and avoided during...
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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].

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) in adults [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 embryo-fetal 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 (on mg/m2 basis) at maternal oral doses up to 1000 mg/kg/day in rats and 300 mg/kg/day in 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 the drug on the breastfed infant, or the effects of the drug on milk production. The lack of clinical data during lactation precludes clear determination of the risk of ESBRIET to an infant during lactation; therefore, the developmental 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.

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, 30–50 mL/min), moderate (CLcr, 10–30 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].

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

Liver Enzyme Elevations
Adverse 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
Adverse 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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1 DNA Way, South San Francisco, CA 94080-4990

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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.
TWO EASY WAYS TO BECOME A NAMDRC MEMBER

1. Go to www.namdrc.org and register for membership online.

2. Mail this application to:

   NAMDRC
   8618 Westwood Center Drive, Suite 210
   Vienna, VA  22182-2273

Please print clearly or type:

NAME (LAST)   (FIRST )   (MIDDLE INITIAL)
____________________________________________________
DEGREE
____________________________________________________
ADDRESS
_____________________________________________________
CITY   STATE   ZIP CODE
_____________________________________________________
TELEPHONE   FAX
_____________________________________________________
E-MAIL
_____________________________________________________

MEMBERSHIP DUES SCHEDULE
(Dues for first year include $75.00 Initiation Fee)

Individual and Small Group Dues............$370.00
Includes groups of up to 6. Please include contact information for all members.

GROUP MEMBERSHIP DUES
(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

TOTAL PAYMENT DUE..........................$_______

PAYMENT
☐ Enclosed is a check payable to NAMDRC (U.S. Dollars)
☐ Change my credit card for total payment due
   ☐ American Express   ☐ VISA   ☐ MASTER CARD

_________________________________________________
CREDIT CARD NUMBER
_________________________________________________
EXPIRATION DATE   SECURITY CODE

NAME AS IT APPEARS ON CREDIT CARD
_________________________________________________
BILLING ADDRESS (IF DIFFERENT FROM REGISTRATION)
_________________________________________________
E-Mail
_________________________________________________

SIGNATURE

In accordance with IRS Regulations, 95% of your 2018 Annual Dues are tax deductible. NAMDRC’s Federal TAX ID # is 74-2020988.

FOR MORE INFORMATION, CONTACT NAMDRC
Phone:  703-752-4359
Fax:  703-752-4360
E-mail:  ExecOffice@namdrc.org
Web Site:  www.namdrc.org