Promoting Medical Device Innovation and Adoption


In the last decade the federal focus on innovation in our medical system has increasingly targeted innovation in physician reimbursement with less emphasis on facilitating the discovery and implementation of new therapies. The Center for Medicare and Medicaid Innovation was established in 2010 by the Affordable Care Act not to speed the adoption of innovative technology but to reduce spending through new payment models. Concerns have been expressed that some of these models will actually discourage the adoption of new technology. The article by Kruklitis et al. recognizes the conflict between the desire to provide the most up to date, effective therapies for our patients with respiratory related disorders and the efforts of payers and administrators to control costs of health care. They state:

With these changes comes an increasing need for physicians to interface with and persuade those purchasers who are often tasked with controlling and reducing costs and ensuring that these technologies provide value to patients and to the system. In this age of innovation and tightened budgets, the pulmonologist not only must practice excellent clinical care but also must evaluate emerging technologies and communicate their impact to the broader organization in tandem.

INSIDE THIS ISSUE:
About NAMDRC…………………9
BOMA Volunteer Notice……………4
Membership Benefits………………..9
NAMDRC Application………………10
NAMDRC Leadership………………3
Product and Technology News- Genentech/Esbriet Article……………5

NAMDRC 41th Annual Meeting and Educational Conference will be held: March 22–24, 2018 Omni La Costa Resort Carlsbad, CA

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“The Washington Watchline is published monthly and provides timely information to NAMDRC members on pending legislative and regulatory issues that impact directly on the practice of pulmonary medicine.

NAMDRC’s primary mission is to improve access to quality care for patients with respiratory disease by removing regulatory and legislative barriers to appropriate treatment.

“NAMDRC will directly affect your practice more than any other organization to which you belong.”
They conclude that:

Pulmonologists must increasingly be advocates of advances in the field and be aware of the challenge to secure investment in emergent technologies that strengthen specialties and improve patient outcomes.

In his article Mr. Porte provides specific examples of barriers to improved patient care and recommendations for addressing those barriers. The examples include appropriate compensation by the Centers for Medicare and Medicaid (CMS) for technologically advanced home mechanical ventilators and high flow oxygen therapy for patients with interstitial lung disease. The article also addresses the impact of the CMS Provider Based Billing rules on expansion of outpatient pulmonary rehabilitation programs. The remedies to the situations identified by Mr. Porte require our national organizations to develop a cooperative and comprehensive plan to advocate for advances in technology and promising therapies.

Our societies have met with success in the past when they work together to address barriers to appropriate patient care. The ACCP, in partnership with the American Thoracic Society and The Campaign for Tobacco Free Kids, was instrumental in the settlement process when the tobacco companies were sued by several state Attorneys General. NAMDRC, in partnership with several societies and patient organizations, convinced the Federal Aviation Administration to allow oxygen concentrators on flights. The ACCP, as participant in the Critical Care Societies Collaborative, successfully worked with the House Commerce Committee to restore the work values to the critical care codes that had been reduced by CMS administrators. As the Hospital Acquired Condition Program was being developed CMS requested NAMDRC participation in the consideration of adding Ventilator Acquired Pneumonia (VAP) and Pulmonary Embolic Disease (DVT/PE) to the list of conditions. NAMDRC comments were instrumental in the CMS decision to not add VAP and to limit the focus of DVT/PE to certain orthopedic procedures. Our comments were quoted in the CMS report published in the Federal Register.

Federal barriers to innovation have become major themes in healthcare in the United States. Research and development in the respiratory technology field are sensitive to changes in the financing and delivery of health care, including the level of reimbursement for improved or new respiratory support technology. In the last decade the balance of determinants of innovation has shifted from factors such as perceived clinical need to cost-efficiency and sociopolitical considerations.

Negotiating compensation for a new medical technology has become increasingly difficult. Medicare is the largest purchaser of healthcare services in the United States and their policies usually set a precedent for commercial insurers.

As healthcare policy has moved into the arena of “value based care”, the federal focus has centered on cost control. Conflicts have arisen between silos of government that are promoting improved quality of care and those preoccupied with cost containment. On the one hand, the CMS Office of Clinical Standards and Quality is profiling physicians on quality measures, such as frequency of readmissions, on the other hand, the availability of advanced medical devices for support of patients with chronic respiratory diseases is impeded by career bureaucrats responsible for coding, coverage and payment decisions.

Innovation in Medical Devices

Within the current Medicare system, a single individual can make a decision on device category, coding, coverage or payment that can prevent a device from entering the marketplace. An office within CMS, the Center for Medicare, is responsible for the development and maintenance of new and revised codes for the Healthcare Common Procedure Coding System. When an application
for a code for a new or modified device is submitted, CMS may
assign either an existing code, a new code, a miscellaneous code
or deny the request for a new code entirely. While all coding
decisions are the responsibility of the central Medicare office, the
vast majority of coding decisions have been deferred to the
Medicare Contractor Medical Directors. These physician adminis-
trators have the power to assign new devices to established code
categories which may or may not be appropriate to the device.
Assignment to the wrong category, with inappropriate reimburse-
ment, can impede the entrance into the marketplace for a new
device. It has been the experience of NAMDRC representatives
that individuals in decision making positions often do not grasp the
intricacies of pulmonary physiology or the sophistication of the
newer technologies.

Payment Mechanisms and Impact on Innovation

Growth in new payment and service delivery models has been
stimulated by the Center for Medicare and Medicaid Innovation;
however, overemphasis on cost control may discourage innovation
and experimentation with new drugs, devices and procedures. A
peer-reviewed study, published in the Journal of Medical Econom-
ics, examined the relationship between insurers’ adoption of
provider payment models to curb costs and approval of coverage
for new items and services made possible by advances in medical
technology. As pay-for-performance and risk sharing programs
increase, administrators shy away from medical technology
advances that have the potential to reduce downstream expenses.

Promoting Medical Device Innovation

A recently published book, Purchasing Medical Innovation, by
James C. Robinson, Professor of Health Economics, University of
California Berkeley, describes the same barriers that have been
encountered by NAMDRC leadership and suggests solutions that
require increased involvement by physician and patient groups.

The Department of Health and Human Services regulatory offices
clearly have important roles to ensure that medical devices are
safe, effective and are correctly reimbursed. The leadership of the
FDA has made efforts to improve the process for medical device
evaluation but have been hampered by insufficient staff, poor train-
ning and high turnover. The 21st Century Cures Bill made substan-
tial changes to the FDA process for approving medical devices.
The most serious obstacle now facing manufacturers is not gaining
FDA approval, but securing a reasonable reimbursement decision
by Medicare. While the previous focus was almost exclusively on
the FDA, start-up companies are now reporting that one of the first
questions that investors now ask is about the prospects for cover-
age and payment. Congress demonstrated an understanding of the
shortcomings of the current CMS process for dealing with new
therapies by requiring more transparency in the establishment of
Local Coverage Decisions by carrier medical directors in the 21st
Century Cures Bill. However, the House Commerce Committee
now needs to be encouraged to take a close look at how decisions regarding billing codes for new devices are currently being deferred to the same administrators by the Center for Medicare.

In his book Robinson points out that development of better evidence by the medical device industry is a crucial element in advancing technology. The major gap in the current application and approval system is the lack of outcome data. This is particularly true for devices in the 501(k) pathway. Advances in information technology allowing data mining of electronic medical records and incentives to develop patient registries can facilitate the acquisition of the relevant information. A number of academic centers have established data centers for building patient-centered and privacy-preserving statistical data registries. The author predicts that comparative effectiveness research will become a foundation for insurance coverage of new and evolving devices.

**NAMDRC’s Role in Advocacy**

Our professional societies, particularly those developing and promoting evidence based guidelines, have a responsibility to ensure that their recommendations are not impeded by inappropriate and poorly informed decisions. With years of advocacy experience, the NAMDRC leadership has built a constructive relationship with federal policy makers and developed an intimate appreciation of the policy making process. This includes both the important relationships as well as the tensions among key agencies such as the Office of Inspector General, the Office of Management and Budget, the relevant divisions within the Centers for Medicare and Medicaid and importantly the Medical Directors of the Medicare contractors. Over the last 39 years, regulatory agencies have come to recognize NAMDRC physicians as a resource of critical and unbiased science that can facilitate their rule making decisions influencing the area of clinical practice. We recognize that Washington DC is a busy place with short term memory and patient care issues are often lost in the shuffle. Effective advocacy in the federal arena requires a daily presence in Washington and frequent communication with the policy makers. NAMDRC provides an open forum for innovative thinkers to identify and prioritize areas for advocacy. The society welcomes input from all individuals interested in the advancement of clinical medicine.

**NOTICE:** NAMDRC is seeking a volunteer to serve as our representative to the Board of Medical Advisors (BOMA) of AARC. This involves participation in two formal meetings per year, one during the summer and one at their fall conference. If you are interested in learning more, please contact NAMDRC Executive Director Phil Porte at Phil@namdrc.org
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 was required in 18.5% of patients in the treated with Esbriet. Dosage reduction or interruption for diarrhea, dyspepsia, vomiting, gastroesophageal reflux disease, exposure. Patients should avoid concomitant medications that (SPF 50 or higher), and wear clothing that protects against sun minimize exposure to sunlight (including sunlamps), use a sunblock with patients treated with placebo (1%). Patients should avoid or had a higher incidence of photosensitivity reactions (9%) compared Patients treated with Esbriet function tests (ALT, AST, and bilirubin) prior to initiating Esbriet, or the need for liver transplants in some patients. Conduct liver tests (ALT, AST, and bilirubin) prior to initiating Esbriet, than the first 6 months and every 3 months thereafter. Dosage modifications or interruption may be necessary.

Photosensitivity reaction or rash: Patients treated with Esbriet had a higher incidence of photosensitivity reactions (14%) compared with patients treated with placebo (7%). Patients should avoid or minimize exposure to sunlight (including sunlamps), wear a sunblock (SPF 50 or higher), and wear clothing that protects against sun exposure. Patients should avoid concurrent medications that cause photosensitivity. Dosage reduction or discontinuation may be necessary.

Gastrointestinal disorders: Gastrointestinal events of nausea, diarrhea, dyspepsia, vomiting, gastroesophageal 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 gastrointestinal events, compared to 1.5% in the placebo group. The most common (≥2%) gastrointestinal events that led to dosage reduction or interruption were nausea, diarrhea, vomiting, and dyspepsia. Discharge modifications may be necessary in some cases.

Adverse reactions: The most common adverse reactions (≥10%) were nausea, rash, abdominal pain, upper respiratory tract infection, diarrhea, fatigue, headache, dyspnea, dizziness, vertigo, anorexia, gastrointestinal reflux disease, anemia, insomnia, weight decreased, and dyspnea.

Drug interactions: Concurrent administration with strong inhibitors of CYP1A2 may result in significantly increased 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 a moderate inhibitor of CYP1A2 (moderate inhibitor of CYP1A2) moderately increases exposure to Esbriet. If concomitant at the dosage of 750 mg twice daily cannot be avoided, dosage reductions of Esbriet are recommended. Monitor patients closely when concomitant is used.

Agents that are moderate or strong inhibitors of both CYP1A2 and CYP3A4 are contraindicated in the metabolism of Esbriet and should be avoided during treatment. The concomitant use of a CYP1A2 inhibitor may decrease the exposure of Esbriet and may lead to loss of efficacy. Concurrent use of strong CYP1A2 inhibitors should be avoided.

Specific populations: Esbriet should be used with caution in patients with mild to moderate (G1Hg or Class A or B) hepatic impairment. Monitor for adverse reactions and consider dosage modification or discontinuation of Esbriet as needed. 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. Esbriet should be used with caution in patients with end-stage renal disease requiring dialysis. Use of Esbriet in patients with end-stage renal disease requiring dialysis is not recommended.

Smoking causes decreased exposure to Esbriet, 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. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-825-2555.

Please see Physician’s Prescribing Information for additional Important Safety Information.


Learn more about Esbriet and how to access medication at EsbrietHCP.com

WE WON’T BACK DOWN FROM IPF
Help preserve more lung function. Reduce lung function decline.1–4
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 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>% of Patients (0 to 118 Weeks)</th>
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<tbody>
<tr>
<td>Nausea</td>
<td>ESBRIET 36% vs. Placebo 16%</td>
</tr>
<tr>
<td>Rash</td>
<td>ESBRIET 30% vs. Placebo 10%</td>
</tr>
<tr>
<td>Abdominal Pain1</td>
<td>ESBRIET 24% vs. Placebo 15%</td>
</tr>
<tr>
<td>Upper Respiratory Tract Infection</td>
<td>ESBRIET 27% vs. Placebo 25%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>ESBRIET 26% vs. Placebo 20%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>ESBRIET 26% vs. Placebo 19%</td>
</tr>
<tr>
<td>Headache</td>
<td>ESBRIET 22% vs. Placebo 19%</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>ESBRIET 19% vs. Placebo 7%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>ESBRIET 18% vs. Placebo 11%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>ESBRIET 13% vs. Placebo 6%</td>
</tr>
<tr>
<td>Anorexia</td>
<td>ESBRIET 13% vs. Placebo 6%</td>
</tr>
<tr>
<td>Gastro-esophageal Reflux Disease</td>
<td>ESBRIET 11% vs. Placebo 7%</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>ESBRIET 11% vs. Placebo 10%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>ESBRIET 10% vs. Placebo 7%</td>
</tr>
<tr>
<td>Weight Decreased</td>
<td>ESBRIET 10% vs. Placebo 5%</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>ESBRIET 10% vs. Placebo 7%</td>
</tr>
</tbody>
</table>

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

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
- Angioedema
- Hepatobiliary Disorders
- Bilirubin increased in combination with increases of ALT and AST

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. 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 the initial 6 months of treatment.
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) 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 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 (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 > 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].

The safety, efficacy, and pharmacokinetics of ESBRIET have not been studied in patients with end-stage renal disease requiring dialysis. Use of ESBRIET in patients with end-stage renal diseases requiring dialysis is not recommended.

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
Advising 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.

Distributed by:
Genentech USA, Inc.
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1 DNA Way, South San Francisco, CA 94080-4990

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NAMDRG Membership Benefits AT A GLANCE...

- 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.
### NAMDRC MEMBERSHIP APPLICATION

**TWO EASY WAYS TO BECOME A NAMDRC MEMBER**

1. Go to [www.namdrc.org](http://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:

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**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

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**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  
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Web Site: [www.namdrc.org](http://www.namdrc.org)