Bronchial Valves

Medicare Advantage Medical Policy # MA-227
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Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Blue Advantage does not cover investigational or experimental services, including any drug, device, procedure, or service provided under the investigational arm of a clinical trial or study unless mandated by the Centers for Medicare and Medicaid Services. Coverage is limited to routine services for Category A IDE studies and to devices and related services for Category B IDE studies when not supplied by the trial sponsor. Approved IDE studies are posted on www.cms.gov/medicare/coverage/evidence.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Health Plan may consider use of the FDA-approved bronchial valves for treatment of adult patients with hyperinflation and shortness of breath despite optimized medical therapy associated with severe emphysema in regions of the lung that have little to no collateral ventilation to be **eligible for coverage**** (see additional criteria and contraindications in Policy Guidelines section)**.**

Based on review of available data, the Health Plan may consider use of the FDA-approved bronchial valves for treatment of adult patients with prolonged air leaks following lobectomy, segmentectomy, or lung volume reduction surgery causing pneumothorax that is not improving greater than or equal to 5 days after chest tube insertion to be **eligible for coverage.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan considers use of bronchial valves in all other situations to be **investigational.***

Policy Guidelines

Based on the inclusion criteria for the pivotal clinical trials, candidates for endobronchial valve (EBV) placement should meet following criteria:

- Medical history and physical examination
    - Clinical presentation consistent with emphysema
    - Highly symptomatic despite optimal medical therapy and maximal pulmonary rehabilitation

  - Nonsmoking for greater than or equal to 4 months
  - BMI less than 35 kg/m^2
- Pulmonary function tests
  - Marked airflow obstruction on spirometry with forced expiratory volume in one second (FEV_1) greater than or equal to 15% predicted but less than or equal to 45% predicted
  - Lung volume measurements showing air trapping:
    - Total Lung capacity (TLC) greater than or equal to 100% predicted
    - Residual volume (RV) greater than or equal to 175% predicted
  - A six-minute walk distance (6MWD) greater than or equal to 100 m and less than 500 m following supervised pulmonary rehabilitation
- Imaging
  - Hyperinflation and emphysema on high resolution CT scan
  - Intact lobar fissures (greater than or equal to 90% completeness of the fissure separating the target and the adjacent lobe) in targetable lung regions highly affected by emphysema
    - If the fissure separating the target lobe and the adjacent lobe is less than 90% complete on quantitative CT analysis systems (StratX for Zephyr valves or SeleCT for Spiration valves), the lack of collateral ventilation will be confirmed by using the Chartis system (a measurement device used during bronchoscopy and prior to placement of the valves)
- Anesthesia
  - Able to tolerate procedural sedation

Established contraindications for endobronchial valve therapies include:
- Cigarette smoking within the prior four months
- Comorbid cardiac illness that would increase surgical mortality (e.g., significant coronary heart disease, heart failure with a left ventricular ejection fraction less than 40 percent)
- Severe obesity (greater than or equal to 35 kg/m^2)
- Inability to complete a 6- to 10-week program of pulmonary rehabilitation
- Prior cardiothoracic surgery in the ipsilateral pleural space, including lung transplant, LVRS, or lobectomy
- End-stage pulmonary disease as defined by severe resting hypoxemia (arterial partial pressure of oxygen [P_aO_2] less than 45 mmHg), hypercapnia (arterial partial pressure of carbon dioxide (P_aCO_2) greater than 60 mmHg), FEV_1 less than 15 percent predicted, six-minute walk distance less than 100m
- Large bullae encompassing greater than 30% of either lung
- Active pulmonary infection.

Background/Overview

Pulmonary Air Leaks

Proper lung functioning depends on the separation between the air-containing parts of the lung and the small vacuum-containing space around the lung called the pleural space. When air leaks into the pleural space, the lung is unable to inflate, resulting in hypoventilation and hypoxemia; this condition is known as a pneumothorax. A pneumothorax can result from trauma, high airway pressures induced during mechanical ventilation, lung surgery, and rupture of lung blebs or bullae, which may be congenital or a result of chronic obstructive pulmonary disease (COPD).

Emphysema

Emphysema, a form of COPD, is a progressive, debilitating disease characterized by irreversible destruction of alveolar tissue. This destruction results in reduced elastic recoil, progressive hyperinflation, and gas trapping, with patients experiencing chronic dyspnea, limited exercise tolerance, and poor health-related quality of life. In emphysematous COPD, diseased portions of the lung ventilate poorly, cause air trapping, and hyperinflate, compressing relatively normal lung tissue. The patterns and degree of emphysema heterogeneity (i.e., the extent and distribution of air space enlargements) can be measured using computed tomography (CT) density as an indicator for tissue destruction. The most diseased portions of lung can then potentially be targeted for lung volume reduction procedures. In homogeneous emphysema, there is minor or no regional difference in disease within or between lobes of the lung.

In the United States, the prevalence of COPD varies widely by state, with the estimated prevalence in 2021 ranging from <4.5% in California, the District of Columbia, Hawaii, and Utah to >9% in Kentucky, Mississippi, Tennessee, and West Virginia. In 2018, chronic lower respiratory disease, primarily COPD, was the fourth leading cause of death in the United States. COPD mortality has decreased among Americans overall, but this decline has not been observed in all sociodemographic groups. An analysis of COPD mortality between 2004 and 2018 found that African American women were the only sociodemographic group to have had an increase in COPD mortality, with an annual percent change (APC) of 1.3% (95% confidence interval [CI], 0.9% to 1.6%), compared to a decrease in men (APC -1.2%; 95% CI, -1.5% to -0.9%), and no change for women overall.

The Global Initiative for Chronic Obstructive Lung Disease, or GOLD, system is commonly used to categorize patients with emphysema according to severity. Stages of airflow limitation are based on the forced expiratory volume in 1 second (FEV1), or the amount of air a person can force out in 1 second after taking a deep breath. Patients with an FEV1 of less than 50% of their predicted value are considered to have severe airflow limitation. Patients are also grouped in the GOLD system using the ABE assessment tool according to categories of risk of having an exacerbation. These groups are based on the number and type of exacerbations per year and self-reported symptoms such as breathlessness. Of note, group E was previously divided into 2 separate groups, but was merged in 2023 to highlight the clinical significance of exacerbations.

Table 1. Classification of Disease Severity

Stages of Airflow Limitation	Severity Grouping
• GOLD 1 (**mild**): FEV1 ≥80% predicted • GOLD 2 (**moderate**): 50% ≤ FEV1 <80% predicted • GOLD 3 (**severe**): ○ 30% ≤ FEV1 <50% predicted • GOLD 4 (**very severe**): FEV1 <30% predicted	**Group A:** 0 to 1 exacerbation per year, not requiring hospitalization, fewer symptoms **Group B:** 0 to 1 exacerbation per year, not requiring hospitalization, more symptoms **Group E:** ≥2 exacerbations per year, or 1 or more requiring hospitalization

FEV1: forced expiratory volume in 1 second; GOLD: Global Initiative for Chronic Obstructive Lung Disease.

Bronchial Valves
Bronchial valves are synthetic devices deployed with bronchoscopy into ventilatory airways of the lung to control airflow. During inhalation, the valve is closed, preventing air flow into the diseased area of the lung. The valve opens during exhalation to allow air to escape from the diseased area of the lung. They have been investigated for use in patients who have prolonged bronchopleural air leaks and in patients with lobar hyperinflation from severe or advanced emphysema.

When used to treat persistent air leaks from the lung into the pleural space, the bronchial valve theoretically permits less air flow across the diseased portion of the lung during inhalation, aiding in air leak closure. The valve may be placed, and subsequently removed, by bronchoscopy.

The use of bronchial valves to treat emphysema is based on the improvement observed in patients who have undergone lung volume reduction surgery. Lung volume reduction surgery involves excision of peripheral emphysematous lung tissue, generally from the upper lobes. The precise mechanism of clinical improvement for patients undergoing lung volume reduction has not been firmly established. However, it is believed that elastic recoil and diaphragmatic function are improved by reducing the volume of the diseased lung. Currently, and at the time the clinical trials were designed, very few lung volume reduction procedures were performed. The procedure is designed to relieve dyspnea and improve functional lung capacity and quality of life; it is not curative. Medical management remains the most common treatment for a majority of patients with severe emphysema.

In early trials of bronchial valves for treatment of emphysema, absence of collateral ventilation (pathways that bypass the normal bronchial airways) was associated with better outcomes, presumably because patients with collateral ventilation did not develop lobar atelectasis (collapse). In subsequent trials, patients were selected for absence of collateral ventilation, and it is current practice for patients to be assessed for the presence of collateral ventilation prior to undergoing the procedure. Collateral ventilation is measured by the Chartis System, which requires bronchoscopy, or as a surrogate, CT scanning to assess the completeness of fissures. After 45 days post-procedure, residual volume can provide information on whether lung volume reduction has been achieved successfully.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In October 2008, the Spiration®‡ IBV Valve System (Spiration) was approved by the U.S. Food and Drug Administration (FDA) through the humanitarian device exemption (H060002) process for use in controlling prolonged air leaks of the lung or significant air leaks that are likely to become prolonged air leaks following lobectomy, segmentectomy, or lung volume reduction surgery. An air leak present on postoperative day 7 is considered prolonged unless present only during forced exhalation or cough. An air leak present on day 5 should be considered for treatment if it is: (1) continuous, (2) present during the normal inhalation phase of inspiration, or (3) present on normal expiration and accompanied by subcutaneous emphysema or respiratory compromise. Use of the Intrabronchial Valve System is limited to 6 weeks per prolonged air leak. FDA product code: OAZ.

Two bronchial valve systems are FDA approved for treatment of patients with severe emphysema. In June 2018, FDA granted the Zephyr Valve system breakthrough device status with expedited approval for the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation. In December 2018, FDA approved the Spiration Valve System for adult patients with shortness of breath and hyperinflation associated with severe emphysema in regions of the lung that have evidence of low collateral ventilation. FDA product code: NJK.

Table 2. Bronchial Valve Systems Approved by FDA

Device	Indication	Manufacturer	Location	Date Approved	HDE/PMA No.
IBV®‡ Valve System	To control prolonged air leaks of the lung, or significant air leaks that are likely to become	Spiration, Inc	Redmond, WA	10/24/08	H060002

	prolonged air leaks, following lobectomy, segmentectomy, or lung volume reduction surgery				
Spiration®‡ Valve System	For adult patients with shortness of breath and hyperinflation associated with severe emphysema in regions of the lung that have evidence of low collateral ventilation	Spiration, Inc	Redmond, WA	12/03/18	P180007
Zephyr®‡ Endobronchial Valve System	For the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation	Pulmonx Corporation	Redwood City, CA	06/29/18	P180002

FDA: Food and Drug Administration, HDE: human device exemption; PMA: premarket approval application.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration

approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Bronchial valves are synthetic devices deployed with bronchoscopy into ventilatory airways of the lung to control airflow. They have been investigated for use in individuals who have prolonged bronchopleural air leaks and in individuals with lobar hyperinflation from severe or advanced emphysema.

Summary of Evidence
For individuals who have pulmonary air leaks who receive bronchial valves, the evidence includes a systematic review, case series, and a prospective cohort observational study related to the Humanitarian Device Exemption for the Spiration IBV Valve device. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related morbidity. Other reports are small series of heterogeneous patients, including a systematic review of these data. There are no comparative data with alternatives. This evidence is inadequate to determine the impact of this technology on the net health outcome. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have severe or advanced emphysema with little or no collateral ventilation between target and ipsilateral lobe who receive bronchial valves, the evidence includes multiple randomized controlled trials (RCTs) comparing bronchial valves to usual care at 6 or 12 months, 1 RCT comparing bronchial valves to lung volume reduction surgery (LVRS) through 12 months, systematic reviews, a single center prospective cohort study with patient-reported outcomes, and a prospective cohort study comparing 2 different one-way valve devices. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related morbidity. The RCTs provide evidence of clinically meaningful benefit for bronchial valves compared to standard medical management on measures of lung function, exercise tolerance, and quality of life. However, confidence in these results is low due to study limitations, including a lack of blinding and wide confidence intervals around the estimates of effect. Across studies, there was an increased risk of serious procedure-related adverse events compared to usual care, including pneumothorax occurring in up to 27% of patients. Results at 24 months have been published from one RCT (EMPROVE), with evaluable data from 114 of 172 participants (66.3%). Between the 12-month visit and 24-month visit, 10 participants died (8 intervention and 2 control). Change from baseline in FEV1 remained significantly improved in the treatment group compared to control group through 24 months, but the FEV1 responder rate (15% or greater improvement from baseline) at 24 months did not differ between groups (19.7% treatment vs 13.3% control; P =.57). Acute exacerbations of COPD at the 24-month follow-up occurred in 13.7% (14 of 102) and 15.6% (7 of 45) of individuals in the treatment and control groups, respectively (P =.80). Significant improvements were maintained through 24 months on some, but not all, measures of quality of life. A RCT (CELEB) that compared bronchial valves to LVRS in 80 individuals found no statistically significant difference between treatment groups on the primary outcome (change from baseline to 12 months

on the iBODE instrument, -0.27 (-0.62 to 1.17; P =.54). Notably, the magnitude of change from baseline for both groups on the i-BODE was below the 1.5-point difference considered by the study investigators to be sufficiently clinically important. The trial was limited by lack of participant blinding, high loss to follow-up, choice of a composite primary outcome, and evidence of selective outcome reporting. More participants in the bronchial valve group required additional procedures post-intervention, including 4 (8.5%) who went on to LVRS. In a prospective cohort study of patient-reported outcomes 1 year following treatment, 74.8% were satisfied with the treatment, 52.6% were satisfied with the reduction in their symptoms after treatment, and 91.4% said they would recommend the treatment to others. Confidence in these findings is limited by the study's uncontrolled design and high loss to follow-up (29.9%). The potential benefits of the procedure do not outweigh the demonstrated harms. In another prospective cohort study, there were no statistically significant differences between the Zephyr and Spiration one-way valve devices with regards to lung function, symptom burden, quality of life, or adverse events. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Global Initiative for Chronic Obstructive Lung Disease (GOLD)

The 2025 GOLD publication makes the following recommendations and statements on lung volume reduction interventions (see Figure 3.27 in the GOLD publication):

- "In select patients with advanced emphysema, bronchoscopic interventions reduce end-expiratory lung volume and improve exercise tolerance, health status, and lung function at 6 to 12 months following treatment. Endobronchial valves (Evidence A); lung coils (Evidence B); vapor ablations (Evidence B)." Per the guideline, Evidence category A includes data from: "well-designed randomized controlled trials that provide consistent findings in the population for which the recommendation is made without any important limitations...or high quality evidence from 2 or more clinical trials involving a substantial number of subjects, or a single high quality randomized controlled trial involving substantial numbers of patient without any bias."
- "In selected patients with heterogeneous or homogenous emphysema and significant hyperinflation refractory to optimized medical care, surgical or bronchoscopic modes of lung volume reduction (e.g., endobronchial one-way valves, lung coils or thermal ablation) may be considered."
- "In select patients with advanced emphysema refractory to optimized medical care, surgical or bronchoscopic interventional treatments may be beneficial."

National *Institute* for Health and Care Excellence (NICE)
In December 2017, NICE issued the following recommendations on endobronchial valve insertion to reduce lung volume in emphysema:

1.1 Current evidence on the safety and efficacy of endobronchial valve insertion to reduce lung volume in emphysema is adequate in quantity and quality to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.

1.2 Patient selection should be done by a multidisciplinary team experienced in managing emphysema, which should typically include a chest physician, a radiologist, a thoracic surgeon and a respiratory nurse.

1.3 Patients selected for treatment should have had pulmonary rehabilitation.

1.4 The procedure should only be done to occlude volumes of the lung where there is no collateral ventilation, by clinicians with specific training in doing the procedure.

NICE guidance on the diagnosis and management of COPD (2018, updated 2019) included the following recommendations on lung volume reduction procedures:

Offer a respiratory review to assess whether a lung volume reduction procedure is a possibility for people with COPD when they complete pulmonary rehabilitation and at other subsequent reviews, if all of the following apply:

- they have severe COPD, with FEV1 less than 50% and breathlessness that affects their quality of life despite optimal medical treatment
- they do not smoke
- they can complete a 6-minute walk distance of at least 140 m (if limited by breathlessness).

At the respiratory review, refer the person with COPD to a lung volume reduction multidisciplinary team to assess whether lung volume reduction surgery or endobronchial valves are suitable if they have:

- hyperinflation, assessed by lung function testing with body plethysmography **and**
- emphysema on unenhanced CT chest scan **and**
- optimised treatment for other comorbidities.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some ongoing and unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01796392[a]	Lung Function Improvement After Bronchoscopic Lung Volume Reduction With Pulmonx Endobronchial Valves Used in Treatment of Emphysema (LIBERATE)	190	Apr 2024 (post approval study, 5-year extension)
NCT04186546[a]	Zephyr Valve Registry (ZEVR)	150	Dec 2026
NCT04302272[a]	The Spiration Valve System (SVS) Post-Market Registry Study for Severe Emphysema	150	Apr 2028

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Policy History

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06/16/2026 Utilization Management Committee review/approval. New policy.
Next Scheduled Review Date: 06/2027

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	31647, 31648, 31649, 31651
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan's Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Blue Advantage), Blue Advantage may honor the previous health plan's authorization

for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Blue Advantage health plan.

Medicare Advantage Members
Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.