



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

## Zoledronic Acid (Zometa<sup>®</sup>, Reclast<sup>®</sup>)

Policy # 00191

Original Effective Date: 05/01/2008

Current Effective Date: 04/23/2014

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### ZOMETA<sup>®†</sup>

#### When Services Are 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 Company may consider the use of Zometa for the treatment of any of the following listed conditions to be **eligible for coverage**:

- Patient has hypercalcemia of malignancy (HCM); or
- Patient has multiple myeloma; or
- Patient has documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy; or
- Patient has documented bone metastases associated with prostate cancer AND the disease has progressed following treatment with at least one course of hormonal therapy; or
- Patient has osteolytic lesions due to metastases; or
- Use in prophylaxis of drug-induced osteopenia due to androgen deprivation therapy for prostate cancer; or
- Use in prophylaxis of drug-induced osteopenia due to hormone therapy for breast cancer.

### RECLAST<sup>®†</sup>

#### 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.*

#### Osteoporosis in Men or Postmenopausal Women

Based on review of available data, the Company may consider the use of Reclast for the treatment of osteoporosis in men or postmenopausal women to be **eligible for coverage**.

#### Patient Selection Criteria

Coverage eligibility will be considered for the treatment of osteoporosis with Reclast when all of the following criteria are met:



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- The patient is a man or postmenopausal woman who has central dual x-ray absorptiometry (DXA) bone mineral density (BMD) T-score less than or equal to -2.5, confirming osteoporosis, OR a fragility fracture (hip or vertebral); and
  - o The patient has or has had one of the following:
    - An inability to take oral bisphosphonates; or
    - A 12-month trial of oral bisphosphonates without documented improvement  
(*Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met.*)

## **Prevention of Osteoporosis**

Based on review of available data, the Company may consider the use of Reclast for the prevention of osteoporosis in postmenopausal women to be **eligible for coverage**.

### **Patient Selection Criteria**

Coverage eligibility will be considered for the prevention of osteoporosis with Reclast when the following criteria are met:

- The patient is a postmenopausal woman who is osteopenic (T score between -1.0 and -2.5); AND
- The patient has or has had one of the following:
  - o An inability to take oral bisphosphonates; or
  - o A 12-month trial of oral bisphosphonates without documented improvement.  
(*Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met.*)

## **Adult Individuals with Paget's Disease**

Based on review of available data, the Company may consider the use of Reclast for the treatment of adult individuals with Paget's disease of bone to induce remission (normalization of serum alkaline phosphatase [SAP]) to be **eligible for coverage**.

### **Patient Selection Criteria**

The use of Reclast to induce remission in adult individuals with Paget's disease of the bone may be considered eligible for coverage when any of the following criteria are met:

- The patient's serum alkaline phosphatase elevations are two times or higher than the upper limit of the age specific normal reference range; or
- The patient is symptomatic; or
- The patient is at risk for complications from the disease.

## **Treatment/Prevention of Glucocorticoid-Induced Osteoporosis**

Based on review of available data, the Company may consider the use of Reclast for the treatment and prevention of glucocorticoid induced osteoporosis in patients expected to be on glucocorticoids for at least 12 months to be **eligible for coverage**.



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## 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 Company considers the use of zoledronic acid when any of the following occur to be **investigational\***:

- The use of Zometa for the treatment of conditions not listed; or
- The use of Reclast for any condition not listed or when patient selection criteria for a certain condition are not met (**except** in the absence of a 12-month trial of bisphosphonates for the treatment/prevention of osteoporosis in postmenopausal women or for the treatment of osteoporosis in men which will be denied as **not medically necessary\*\***).

## When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Reclast in the absence of a 12-month trial of bisphosphonates for the treatment/prevention of osteoporosis in postmenopausal women or for the treatment of osteoporosis in men to be **not medically necessary.\*\***

## Background/Overview

Zoledronic acid is an inhibitor of osteoclast-mediated bone resorption. Reclast and Zometa are brand names for zoledronic acid, yet each carries its own indications. Reclast is indicated for the treatment and prevention of osteoporosis in postmenopausal women, treatment to increase bone mass in men with osteoporosis, treatment and prevention of glucocorticoid-induced osteoporosis, and for the treatment of Paget's disease of bone in men and women. Reclast is provided in 5mg/100mL bottles. Zometa is approved for HCM, multiple myeloma, and bone metastases from solid tumors (in conjunction with standard antineoplastic therapy). In prostate cancer patients, the cancer should have progressed after treatment with at least one hormonal therapy before use of Zometa is appropriate. Zometa is provided in a 4mg/100mL ready to use bottle and a 4mg/5mL single use vial of concentrate.

Osteoporosis, a common bone disorder affecting humans and especially elderly postmenopausal women, is characterized by compromised bone strength, which predisposes patients to fractures. Hip and spine fractures are associated with high morbidity and mortality. Osteoporosis is generally defined as a BMD score 2.5 standard deviations (SD) below that of a young normal adult (T score at or below -2.5). In addition to those patients with a DXA score representing osteoporosis, treatment should be considered in those patients with a fragility fracture of the hip or vertebral area. A fragility fracture is any fracture that is caused by a fall from a standing height or less.

The North American Menopause Society (NAMS), which issued guidelines in 2006, considers bisphosphonates as first-line therapy for postmenopausal women. The National Osteoporosis Foundation (NOF) guidelines from 2005 recommend oral bisphosphonates (e.g. resedronate, alendronate, ibandronate) as Food and Drug Administration (FDA)-approved therapies for the prevention and/or treatment of postmenopausal osteoporosis. Guidelines by the Belgian Bone Club in 2006 regarding the prevention and treatment of glucocorticoid-induced osteoporosis (GIO) note that data available for the oral

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bisphosphonates (e.g. etidronate, alendronate, risedronate, pamidronate) show that these agents have been proven efficacious.

Paget's disease of the bone is a chronic disease of the adult skeleton that typically occurs in middle or advanced age. In the U.S. approximately 1 percent of the population over age 40 years is affected. Paget's disease typically involves one bone or a few bones, which are primarily in the skull or pelvis, or a vertebra, femur or tibia. Most clinical manifestations are skeletal and symptoms include mild-to-moderate, deep aching bone pain. The cause of Paget's disease is uncertain, but both genetic and environmental factors may contribute. Elevations in serum alkaline phosphate levels not explained by other causes are a factor in diagnosis and radiographic assessment is also a confirmatory measure. Pharmacologic therapy for Paget's disease includes various oral bisphosphonates, IV pamidronate, IV zoledronic acid and salmon calcitonin by subcutaneous injections. Among the bisphosphonates, alendronate, risedronate, IV zoledronic acid and IV pamidronate are more potent for inhibiting bone turnover and induce a more rapid, complete and sustained biochemical response compared with zoledronic acid injection (Reclast). After a first treatment course, the oral bisphosphonates normalize markers of bone turnover and biochemical remission can occur 6 to 18 months or longer after a single course. Upper gastrointestinal (GI) irritation is a side effect of oral bisphosphonates that can be avoided by use of IV products, pamidronate and zoledronic acid. One review notes that zoledronic acid 5mg as an IV infusion was associated with normalization of SAP in 89% of patients and a prolonged biochemical remission, making it the most effective therapy available to date.

## **FDA or Other Governmental Regulatory Approval**

### **U.S. FDA**

On August 20, 2001 the FDA initially approved Zometa for the treatment of HCM and has since released supplemental approvals for the treatment of other oncology-related indications.

April 16, 2007 the FDA approved Reclast for use in the treatment of Paget's disease in men and women. In August 2007, the FDA approved Reclast as the first once-a-year drug for the treatment of osteoporosis in postmenopausal women. In 2009, Reclast was approved for the treatment of osteoporosis in men. During that same year, it was also approved for the prevention of postmenopausal osteoporosis.

## **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

## **Reclast**

### **Treatment of Post-Menopausal Osteoporosis**

Study 1: The efficacy and safety of Reclast in the treatment of postmenopausal osteoporosis was demonstrated in Study 1 in women aged 65-89 years (mean age of 73) with either: a femoral neck BMD T-score less than or equal to -1.5 and at least two mild or one moderate existing vertebral fracture(s); or a femoral neck BMD T-score less than or equal to -2.5 with or without evidence of an existing vertebral



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fracture(s). Women were stratified into two groups: Stratum I: no concomitant use of osteoporosis therapy or Stratum II: baseline concomitant use of osteoporosis therapies which included calcitonin, raloxifene, tamoxifen, and hormone replacement therapy, but excluded other bisphosphonates. Women enrolled in Stratum I (n = 5661) were evaluated annually for incidence of vertebral fractures. All women (Strata I and II) were evaluated for the incidence of hip and other clinical fractures. Reclast was administered once a year for three consecutive years, as a single 5mg dose in 100mL solution infused over at least 15 minutes, for a total of three doses. The two primary efficacy variables were the incidence of morphometric vertebral fractures at three years and the incidence of hip fractures over a median duration of three years. Reclast significantly decreased the incidence of new vertebral fractures at one, two, and three years. Reclast significantly increased BMD at the lumbar spine, total hip and femoral neck, relative to treatment with placebo at time points 12, 24, and 36 months.

Study 2: The efficacy and safety of Reclast in the treatment of patients with osteoporosis who suffered a recent low-trauma hip fracture was demonstrated in Study 2 in men and women aged 50-95 years (mean age of 74.5). The primary efficacy variable was the incidence of clinical fractures over the duration of the study. Reclast significantly reduced the incidence of any clinical fracture by 35%. There was also a 46% reduction in the risk of a clinical vertebral fracture. Reclast significantly increased BMD relative to placebo at the hip and femoral neck at all timepoints (12, 24, and 36 months). Treatment with Reclast resulted in a 6.4% increase in BMD at the total hip and a 4.3% increase at the femoral neck over 36 months as compared to placebo.

## **Prevention of Postmenopausal Osteoporosis**

The efficacy and safety of Reclast in postmenopausal women with osteopenia (low bone mass) was assessed in a 2-year randomized study of postmenopausal women aged greater than or equal to 45 years, who were stratified by years since menopause: Stratum I women less than 5 years from menopause; Stratum II women greater than or equal to 5 years from menopause. Patients within Stratum I and II were randomized to one of three treatment groups: (1) Reclast given at randomization and at Month 12 in Stratum I and in Stratum II; (2) Reclast given at randomization and placebo at Month 12 in Stratum I and in Stratum II; and (3) Placebo given at randomization and Month 12. The primary efficacy variable was the percent change of BMD at 24 Months relative to baseline. Reclast significantly increased lumbar spine BMD relative to placebo at Month 24 across both strata. Reclast given once at randomization (and placebo given at Month 12) resulted in 4.0% increase in BMD in Stratum I patients and 4.8% increase in Stratum II patients over 24 months. Placebo given at randomization and at Month 12 resulted in 2.2% decrease in BMD in Stratum I patients and 0.7% decrease in BMD in Stratum II patients over 24 months. Therefore, Reclast given once at randomization (and placebo given at Month 12) resulted in a 6.3% increase in BMD in Stratum I patients and 5.4% increase in Stratum II patients over 24 months as compared to placebo (both  $p < 0.0001$ ). Reclast also significantly increased total hip BMD relative to placebo at Month 24 across both strata. Reclast given once at randomization (and placebo given at Month 12) resulted in 2.6% increase in BMD in Stratum I patients and 2.1% in Stratum II patients over 24 months. Placebo given at randomization and at Month 12 resulted in 2.1% decrease in BMD in Stratum I patients and 1.0% decrease in BMD in Stratum II patients over 24 months. Therefore, Reclast given once at randomization (and placebo given at Month 12) resulted in a 4.7% increase in BMD in Stratum I patients and 3.2% increase in Stratum II patients over 24 months as compared to placebo (both  $p < 0.0001$ ).

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## **Osteoporosis in Men**

The efficacy and safety of Reclast in men with osteoporosis or significant osteoporosis secondary to hypogonadism, was assessed in study of men aged 25-86 years. The duration of the trial was two years. Patients were randomized to either Reclast or to an oral weekly bisphosphonate (active control) for up to two years. An annual infusion of Reclast was non-inferior to the oral weekly bisphosphonate active control based on the percentage change in lumbar spine BMD at Month 24 relative to baseline (Reclast: 6.1% increase; active control: 6.2% increase).

## **Glucocorticoid-Induced Osteoporosis**

The efficacy and safety of Reclast to prevent and treat GIO was assessed in a randomized, multicenter, double-blind, stratified, active controlled study of men and women aged 18-85 years treated with greater than or equal to 7.5mg/day oral prednisone (or equivalent). Patients were stratified according to the duration of their pre-study corticosteroid therapy: less than or equal to 3 months prior to randomization (prevention subpopulation), and greater than 3 months prior to randomization (treatment subpopulation). Patients were randomized to either Reclast or to an oral daily bisphosphonate (active control) for one year. In the GIO treatment subpopulation, Reclast demonstrated a significant mean increase in lumbar spine BMD compared to the active control at one year (Reclast 4.1%, active control 2.7%) with a treatment difference of 1.4% ( $p < 0.001$ ). In the GIO prevention subpopulation, Reclast demonstrated a significant mean increase in lumbar spine BMD compared to active control at one year (Reclast 2.6%, active control 0.6%) with a treatment difference of 2.0% ( $p < 0.001$ ).

## **Treatment of Paget's Disease of Bone**

Reclast was studied in male and female patients with moderate to severe Paget's disease of bone, defined as SAP level at least twice the upper limit of the age-specific normal reference range at the time of study entry. The efficacy of one infusion of 5mg Reclast vs. oral daily doses of 30mg risedronate for two months was demonstrated in two identically designed six-month randomized, double blind trials. Therapeutic response was defined as either normalization of SAP or a reduction of at least 75% from baseline in total SAP excess at the end of six months. Serum alkaline phosphatase excess was defined as the difference between the measured level and midpoint of normal range. In both trials Reclast demonstrated a superior and more rapid therapeutic response compared with risedronate and returned more patients to normal levels of bone turnover, as evidenced by biochemical markers of formation (SAP, serum N-terminal propeptide of type I collagen [P1NP]) and resorption (serum CTx 1 [cross-linked C-telopeptides of type I collagen] and urine alpha CTx). The six-month combined data from both trials showed that 96% (169/176) of Reclast-treated patients achieved a therapeutic response as compared with 74% (127/171) of patients treated with risedronate. In addition, at six months, 89% (156/176) of Reclast-treated patients achieved normalization of SAP levels, compared to 58% (99/171) of patients treated with risedronate ( $p < 0.0001$ ). At six months, the percentage of Reclast-treated patients who achieved therapeutic response was 97% and 95%, respectively, in each of the baseline disease severity subgroups (baseline SAP less than 3xULN, greater than or equal to 3xULN) compared to 75% and 74%, respectively, for the same disease severity subgroups of risedronate-treated patients. In patients who had previously received treatment with oral bisphosphonates, therapeutic response rates were 96% and 55% for Reclast and risedronate, respectively. The comparatively low risedronate response was due to the low response rate (7/23, 30%) in patients previously treated with risedronate. In patients naïve to previous treatment, a greater therapeutic response

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was also observed with Reclast (98%) relative to risedronate (86%). In patients with symptomatic pain at screening, therapeutic response rates were 94% and 70% for Reclast and risedronate respectively. For patients without pain at screening, therapeutic response rates were 100% and 82% for Reclast and risedronate respectively.

## Zometa

### **Hypercalcemia of Malignancy**

Two identical multicenter, randomized, double-blind, double-dummy studies of Zometa 4mg given as a 5-minute intravenous infusion or pamidronate 90mg given as a 2-hour intravenous infusion were conducted in patients with HCM. The primary efficacy variable was the proportion of patients having a complete response, defined as the lowering of the corrected serum calcium (CSC) to less than or equal to 10.8mg/dL (2.70mmol/L) within 10 days after drug infusion. To assess the effects of Zometa versus those of pamidronate, the two multicenter HCM studies were combined in a preplanned analysis. The results of the primary analysis revealed that the proportion of patients that had normalization of CSC by Day 10 were 88% and 70% for Zometa 4mg and pamidronate 90mg, respectively (P = 0.002).

### **Multiple Myeloma and Bone Metastases of Solid Tumors**

Various studies were performed in patients with multiple myeloma as well as patients with bone metastases of solid tumors. Each study looked at skeletal related events (SREs). Placebo controlled trials were conducted in patients with prostate cancer as well as patients with other solid tumors. Both trials showed a decrease in the proportion of patients with SRE in the Zometa group. Patients with a diagnosis of multiple myeloma or breast cancer were placed in trials where they were controlled with pamidronate. The proportion of patients with SREs was lower in the Zometa group, and showed no difference as compared to the pamidronate group.

## References

1. Food and Drug Administration. Labeling of the Drug Zometa. November, 2012.
2. Food and Drug Administration. Labeling of the Drug Reclast. April, 2013.
3. Calis, Karim, et.al. Zoledronic Acid and Secondary Prevention of Fractures. The New England Journal of Medicine, September 17, 2007.
4. Black DM, Delmas PD, Eastell R, Reid IR, Boonen S, Cauley JA et al. Once-yearly zoledronic acid for treatment of postmenopausal osteoporosis. N Engl J Med 2007; 356: 1809-22.
5. Zometa<sup>®</sup> (zoledronic acid) Injection [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. November, 2012.
6. Reclast<sup>®</sup> (zoledronic acid) Injection [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. April, 2013.

## Coding

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT<sup>®</sup>)<sup>‡</sup>, copyright 2013 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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CPT is a registered trademark of the American Medical Association.

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

Code Type	Code
CPT	No codes
HCPCS	J3489 (Codes J3487 and J3488 were deleted as of 01/01/2014)
ICD-9 Diagnosis	185, 198.5, 203.00, 203.01, 203.02, 275.42, 731.0, 733.00 thru 733.97, V87.44, V87.45
ICD-9 Procedure	No codes

## Policy History

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12/12/2007 Medical Director review  
 12/19/2007 Medical Policy Committee approval. Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.

07/02/2008 Medical Director review  
 07/16/2008 Medical Policy Committee approval. Added new FDA indication for prevention of new clinical fractures in patients who have suffered low-trauma hip fractures.

02/04/2009 Medical Director review  
 02/19/2009 Medical Policy Committee approval. Added new FDA indication for Reclast for osteoporosis in men to coverage criteria.

04/02/2009 Medical Director review  
 04/15/2009 Medical Policy Committee approval. Added "Based on review of available data, the Company may consider the use of Reclast for adult men or women 18 years of age or older expected to be on glucocorticoids for at least 12 months to be **eligible for coverage**" to the Reclast coverage section.

07/02/2009 Medical Director review  
 07/22/2009 Medical Policy Committee approval. Added "Based on review of available data, the Company may consider the use of Reclast for prevention of osteoporosis in postmenopausal women to be **eligible for coverage**" to the Reclast coverage section.

09/03/2009 Medical Policy Committee approval  
 09/16/2009 Medical Policy Implementation Committee approval. Omitted dosage of once every two years for Reclast in the prevention of osteoporosis. No change to coverage eligibility.

12/04/2009 Medical Policy Committee approval  
 12/16/2009 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
 09/09/2010 Medical Policy Committee review  
 09/15/2010 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
 09/01/2011 Medical Policy Committee review

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09/14/2011 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
10/06/2011 Medical Policy Committee review  
10/19/2011 Medical Policy Implementation Committee approval. Added a *Note* to the Reclast criterion regarding the 12-month trial of oral bisphosphonates without documented improvement. Noted that the reason for denial will be not medically necessary if this criterion is not met. The not medically necessary denial statement for Reclast is also incorporated into the Investigational and Not Medically Necessary coverage sections.  
10/11/2012 Medical Policy Committee review  
10/31/2012 Medical Policy Implementation Committee approval. No change to coverage.  
10/03/2013 Medical Policy Committee review  
10/16/2013 Medical Policy Implementation Committee approval. Aesthetic changes only per Pharmacy Department. Coverage eligibility unchanged.  
04/03/2014 Medical Policy Committee review  
04/23/2014 Medical Policy Implementation Committee approval. Added fragility fracture as an option for treatment as an alternative for T score in the treatment of osteoporosis.  
Next Scheduled Review Date: 04/2015

\*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. 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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.

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