# National Medical Policy

**Subject:** Percutaneous Sacroplasty  
**Policy Number:** NMP438  
**Effective Date:** October 2008  
**Updated:** May 2016

This National Medical Policy is subject to the terms in the IMPORTANT NOTICE at the end of this document

or Medicaid Plans: Please refer to the appropriate State’s Medicaid manual(s), publication(s), citation(s), and documented guidance for coverage criteria and benefit guidelines prior to applying Health Net Medical Policies

## The Centers for Medicare & Medicaid Services (CMS)

For Medicare Advantage members please refer to the following for coverage guidelines first:

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| X    | Local Coverage Determination (LCD)* | PERCUTANEOUS VERTEBRAL Augmentation: Vertebroplasty, Vertebral Augmentation; Percutaneous:  
|      |                               | Update of the Hospital Outpatient Prospective Payment System (OPPS):  
| X    | Other                         | Use Health Net Policy                                                                 |
|      |                               |                                                                                       |

**Instructions**

- Medicare NCDs and National Coverage Manuals apply to ALL Medicare members in ALL regions.
- Medicare LCDs and Articles apply to members in specific regions. To access your specific region, select the link provided under “Reference/Website” and follow the search instructions. Enter the topic and your specific state to find the coverage determinations for your region. *Note: Health Net must follow local coverage*
determinations (LCDs) of Medicare Administration Contractors (MACs) located outside their service area when those MACs have exclusive coverage of an item or service. (CMS Manual Chapter 4 Section 90.2)

- If more than one source is checked, you need to access all sources as, on occasion, an LCD or article contains additional coverage information than contained in the NCD or National Coverage Manual.
- If there is no NCD, National Coverage Manual or region specific LCD/Article, follow the Health Net Hierarchy of Medical Resources for guidance.

Current Policy Statement
Health Net, Inc. considers percutaneous sacroplasty investigational for any indication, including but not limited to the treatment of sacral insufficiency fracture, as the long-term outcomes, safety and efficacy has not been demonstrated in the peer review published literature.

Abbreviations
MRI: Magnetic resonance imaging
CT: Computed tomography
PMMA: Polymethylmethacrylate

Codes Related To This Policy
NOTE:
The codes listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit documents and medical necessity criteria. This list of codes may not be all inclusive.

On October 1, 2015, the ICD-9 code sets used to report medical diagnoses and inpatient procedures have been replaced by ICD-10 code sets.

ICD-9 Codes
714.0  Rheumatoid Arthritis
724.5  Backache, unspecified
724.6  Disorders of sacrum
733.00 - 733.09  Osteoporosis
733.95  Stress fracture of other bone
805.6  Fracture, sacrum and coccyx, closed
990  Effects of radiation, unspecified
V58.65  Long term use of steroids

ICD-10 Codes
M06.811-M06.89  Other specified rheumatoid arthritis
M54.40-M54.9  Lumbago with sciatica
M81.0-M81.8  Osteoporosis without current pathological fracture
M48.40XA-  Fatigue/ stress fracture of vertebra
M84.38XA
M48.40XA-  Fatigue/ stress fracture of vertebra
M84.38XA
S32.10XA-  Fracture of sacrum/ coccyx (closed)
S32.2XXA
T66.XXXA  Radiation sickness, unspecified, initial encounter
Z79.51- Z79.52  Long term (current) use of steriods
CPT Codes

22889  Unlisted procedure, spine
0200T  Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, one or more needles, including imaging guidance and bone biopsy, when performed. (Revised in 2015)
0201T  Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, two or more needles, including imaging guidance and bone biopsy, when performed. (Revised in 2015)

HCPCS Codes
N/A

Scientific Rationale – Update May 2016
Onen et al. (2015) evaluated the clinical results of sacroplasty for sacral insufficiency fracture (SIF). SIF are rare fractures that present as low back and groin pain. The diagnosis of SIF is difficult and sacroplasty is the last line of treatment. The authors reviewed the clinical and radiological data of 15 patients who underwent sacroplasty. Fifteen patients were selected, 12 women and three men, all of whom had failed to respond to medical therapy and bed rest, and were aged 39-76 years (mean 65.7). A retrospective electronic medical record review and face-to-face or phone interview was conducted. The patients' pain was assessed using the visual analogue scale (VAS) and functional status was assessed using the Oswestry disability index (ODI). Radiological diagnoses and investigations were performed using sacral CT scans and MRI. The sacroplasty procedures were performed using the short axis technique. The preoperative VAS scores (mean±standard deviation) were reduced from 7.6±0.7 to 1.7±0.7 postoperatively (p<0.05). The preoperative ODI was also reduced from a mean of 44 (range: 38-46) to 14 (11-22) postoperatively (p<0.05). Sacroplasty is proposed to be an effective and safe procedure to relieve pain due to SIF, per this study. However, this is a retrospective and very small study of only 15 patients. Additional, larger, peer-reviewed, comparative studies with long-term outcomes are necessary to determine if sacroplasty is a safe and effective procedure for sacral insufficiency fractures.

Moussazadeh et al. 2015) completed a prospective study with sacroplasty for tumor-associated lesions, including the largest series to date of radiation-induced sacral insufficiency fractures SIF). Twenty-five patients with symptomatic SIF underwent 31 percutaneous fluoroscopy-guided sacroplasties with a median 5.8 mL of polymethyl methacrylate or a ceramic-resin composite under fluoroscopic guidance and with concurrent biopsy acquisition. Eighteen patients had fractures related to previous sacral or pelvic radiation; 4 had viable lytic lesions; and 2 had oncology-related osteoporosis. Postoperative pain reduction, procedural morbidity, and functional outcomes were recorded. Twenty of 25 patients (80%) had reduction in their visual analog pain score at a median follow-up of 6.5 months; no patients worsened. The mean visual analog scale score decreased from 8.8 to 4.7 postprocedurally (P < .001), with significant reductions regardless of the underlying pathology (P < .001 to P <.05). Six of 13 patients with pretreatment ambulatory impairment required fewer ambulatory aids and 3 were newly ambulatory. Extravertebral cement migration was noted in 18 procedures; however, no instance was clinically relevant. Six repeat or contralateral procedures were performed. No morbidity was encountered. Sacroplasty is proposed to be a safe and effective option
for the palliation of sacral fractures in the oncologic population. However, this is another small prospective study of only 25 patients.

Andresen et al. (2015) completed a study with the objective to evaluate the feasibility of cement augmentation by RFS, as well as to determine post-interventional leakages and present the patients' outcomes. In 20 patients (18 women, 2 men) with an average age of 80.4 (65-92) years, a fracture of the sacrum was detected by CT and MRI. Clinically manifest osteoporosis with QCT values of below 50 mg/ml was found in all patients. An initially performed conservative treatment over a period of 3 weeks did not achieve a satisfactory reduction in the severe, disabling pain. The cement augmentation was performed under CT guidance by means of RFS under intubation anaesthesia. A Jamshidi needle was advanced into the respective fracture zone in the sacrum from dorsal to ventral (short axis) or from lateral to medial transiliac (transiliac axis). After removing the inner needle, a Flexible osteotome was inserted through the positioned hollow needle and used to extend the spongyous space in the fracture zone and thus prepare a cavity for the cement filling. The highly viscous polymethyl methacrylate (PMMA) cement, activated by radiofrequency, was then inserted into the prepared fracture zone through a substituted screw cannula. Cement filling was performed discontinuously under instrumental guidance at 1.3 ml/min under CT guidance. Cement leakages were determined in CT images and conventional X-rays on the day after the intervention. Pain was documented on a visual analogue scale (VAS) on the day before the intervention, on the second day, and after 6 and 12 months after the intervention. Additionally occurring complications were recorded, and the patients were asked to state how satisfied they were after 12 months. RFS was technically feasible in all patients. In the control CT scans and X-rays, sufficient cement distribution and interlocking with vital bone was found along the course of the fracture in the sacrum. 7.2 (4-9) ml of cement were inserted per fracture. Leakage could be ruled out. The mean pain score on the VAS was 8.8 ± 1.2 before the intervention, and a significant reduction in pain (p <0.001) was seen on the second postoperative day, with an average value of 2.3 ±0.7, which was stable at 2.2 ± 1.3 after 6 months and 2.1 ± 1.1 after 12 months. All of the patients could be fully re-mobilised and discharged back home. A high level of patient satisfaction was found after 12 months, with 18 of the 20 patients stating that they would undergo the intervention again. One patient died of a stroke, another of cancer over the course. As a minimally invasive procedure, RFS is an effective and safe method of treatment for rapid, significant and sustained pain reduction. In conclusion, this was another small study of 20 patients with a short 12 month follow-up. Additional, peer-reviewed larger comparative studies with longer follow-up periods are necessary.

**Scientific Rationale – Update May 2015**

There continues to be a paucity of published peer-reviewed studies in medical literature to allow for adequate evaluation of sacroplasty. Small numbers of individuals treated leaves uncertainty regarding the impact of sacroplasty on health outcomes. No new additional studies could be found on percutaneous sacroplasty. Additional controlled studies with long-term assessment of the results of percutaneous sacroplasty are needed to confirm that it is a safe and effective procedure for sacral insufficiency fractures.

**Scientific Rationale – Update May 2014**
Pereira et al (2013) reported their experience in percutaneous sacroplasty (PSP) for tumors and insufficiency fractures of the sacrum in a single-centre retrospective analysis of 58 consecutive patients who underwent 67 PSPs for intractable pain from
sacral tumors (84.5 %) or from osteoporotic fractures (15.5 %). The following data were assessed: visual analogue scale (VAS) before and after the procedure for global pain; short-term (1-month) clinical follow-up using a four-grade patient satisfaction scale (worse, unchanged, mild improvement and significant improvement); modification in analgesics consumption; referred short-term walking mobility. Minor and major complications were systematically assessed. The mean VAS score was 5.3±2.0 in pre-procedure and 1.7±1.8 in post-procedure. At 1-month follow-up, 34/58 (58.5 %) patients experienced a mild improvement; 15/58 (26 %) presented a significant improvement while 4/58 (7 %) and 5/58 (8.5 %) patients had unchanged or worse pain, respectively. Decreased analgesic consumption was observed in 34 % (20/58) of the patients. Eighty percent of patients with walking limitation experienced improvement, 16 % remained unchanged and 4 % were worse. We noted minor complications in 2/58 patients (3.4 %) and major complications in 2/58 patients (3.4 %). The authors concluded percutaneous sacroplasty for metastatic and osteoporotic fractures is a safe and effective technique in terms of pain relief and functional outcome.

Dougherty et al (2014) retrospectively reviewed 57 patients treated with sacroplasty for painful osteoporotic sacral fractures at a single institution between 2004 and 2011. An 11-point numerical rating scale pain score was recorded at rest and at activity pre- and post-procedure. Opioids prescribed to the patient both pre- and post-procedure were recorded. Mean duration of pain prior to sacroplasty was 3 weeks (IQR 2-5). Procedural complications were minimal. Median post-procedure follow-up time was 2.5 weeks (IQR 1-5) among 45 patients with available data. Thirty-seven (82%) of the 45 patients experienced a numerical or descriptive decrease from initial pain at follow-up. Median activity pain scores collected from 13 patients decreased from 10 (IQR 8.5-10) pre-procedure to 6 (IQR 4-6.8) post-procedure (p<0.0001), and median rest pain scores collected from 29 patients decreased from 7 (IQR 4-8.5) to 2 (IQR 1-3.5)(p<0.0001). Twenty-two (76%) of 29 patients had at least a 30% decrease in rest pain scores. The median number of opioids prescribed per patient decreased from 1 (IQR 1-2) pre-procedure to 0 (IQR 0-1) post-procedure (p<0.0001). Thirty-four of 57 patients (60%) had decreased opioid usage, 15 (26%) patients had unchanged usage and 8 (14%) had increased usage. The authors concluded the series demonstrates that sacroplasty is a safe and effective treatment in patients with painful osteoporotic insufficiency fractures.

Kortman et al (2013) assessed the outcomes and safety after CT-guided percutaneous sacroplasty in patients with painful sacral insufficiency fractures or pathologic sacral lesions. A retrospective multicenter analysis of consecutive patients undergoing CT-guided sacroplasty for painful sacral insufficiency fractures or sacral lesions was undertaken. The inclusion criteria consisted of severe sacral pain not responding to conservative medical management with imaging evidence of unilateral or bilateral sacral insufficiency fractures or lesions. Outcome measures included hospitalization status (inpatient or outpatient), pre-treatment and post-treatment visual analog scale (VAS) scores, analgesic use and complications. Patients were followed at approximately 1 month and for at least 1 year after their sacroplasty procedure. Two hundred and forty-three patients were included in the study, 204 with painful sacral insufficiency fractures and 39 with symptomatic sacral lesions. The average pre-treatment VAS score of 9.2±1.1 was significantly improved after sacroplasty to 1.9±1.7 in patients with sacral insufficiency fractures (p<0.001). The average pre-treatment VAS score of 9.0±0.9 in patients with sacral lesions was significantly improved after sacroplasty to 2.6±2.4 (p<0.001). There were no major complications or procedure-related deaths. One patient who was treated for a sacral insufficiency fracture experienced radicular pain due to local extravasation of cement that subsequently required surgical decompression for symptomatic relief. The authors concluded CT-guided percutaneous sacroplasty is a safe and effective
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procedure in the treatment of painful sacral insufficiency fractures or lesions. It is associated with prompt and durable pain relief and should be considered as an effective treatment option in this patient population.

**Scientific Rationale – Update July 2013**
Barber et al. (2013) Percutaneous sacroplasty is a procedure adapted from vertebroplasty, which is designed to ameliorate the painful morbidity associated with sacral insufficiency fractures without the invasiveness of open surgery. Early estimates of efficacy, according to several case reports and small series, appear promising, but the procedure is not without risk. Several cases of radiculopathy due to nerve root compression by extravasated polymethylmethacrylate (PMMA) have been reported. The authors present a case of radiculopathy caused by cement leakage from sacroplasty, treated with surgical decompression of the compromised nerve root. The patient presented with left S-1 radiculopathy and was found on CT to have a left S-1 nerve root completely encased in PMMA over a portion of its length. The patient underwent sacral laminectomy with the removal of PMMA and experienced pain relief and the return of function postoperatively. Surgical removal of PMMA extravasated during sacroplasty is feasible and should be considered when nerve root compression or canal stenosis causes pain or neurological deficit refractory to conservative therapy.

There is an ongoing Clinical Trial on 'Utility of CT Fluoroscopy Guidance During Percutaneous Sacroplasty With Quality of Life Assessment’. The ClinicalTrials.gov Identifier is NCT00765258, and it was last updated on May 7, 2012. The purpose of the trial is to examine, through retrospective and prospective chart review, the difference in pain and mobility, pre and post treatment, as assessed by the patient's completion of the VAS pain scale and Roland Morris Disability Questionnaire (RMDQ). CT fluoroscopy guidance during percutaneous sacroplasty is an effective treatment for sacro-iliac insufficiency fractures resulting in rapid reduction of pain and improved mobility in patients. This can be effectively assessed using the VAS pain scale and RMDQ both pre and post procedure. The estimated primary completion date is December 2014.

**Scientific Rationale – Update October 2010**
Peer review published literature regarding the safety and efficacy of sacroplasty is limited. Randomized controlled studies with long-term follow-up are needed to confirm that percutaneous sacroplasty is a safe and effective procedure for sacral insufficiency fractures.

**Scientific Rationale – Update October 2009**
Kamel et al (2009) investigated nineteen patients with unilateral (n = 3) or bilateral (n = 16) sacral fractures treated with CT-guided sacroplasty using the long-axis approach through a single entry point. An average of 6 ml of polymethylmethacrylate (PMMA) was delivered along the path of each sacral fracture. For each individual patient, the Visual Analogue pain Scale (VAS) before sacroplasty and at 1, 4, 24 and 48 weeks after the procedure was obtained. The use of analgesics (narcotic/non-narcotic) along with the evolution of post-interventional patient mobility before and after sacroplasty was also recorded. The mean VAS rapidly declined in the first week after the procedure followed by a gradual decrease along the rest of the follow-up period at 4 weeks, 24 weeks and 48 weeks. Eleven (58%) patients were under narcotic analgesia before sacroplasty, whereas 8 (42%) patients were using non-narcotics. Corresponding values after the procedure were 2/19 (10%; narcotic, one of them was on reserve) and 10/19 (53%; non-narcotic). The remaining 7 (37%) patients did not address post-procedure analgesic use. The evolution of post-interventional mobility was favorable in the study group as they revealed a
significant improvement in their mobility point scale. The investigator concluded that long-axis percutaneous sacroplasty appears to be a suitable, minimally invasive treatment option for patients who present with sacral insufficiency fractures; however, additional, larger studies are needed to explore this therapeutic approach.

Bayley et al (2009) performed a review of the available literature regarding the outcomes of various operative techniques used in the treatment of sacral insufficiency fractures (SIF), specifically sacroplasty and augmented iliosacral (trans-sacral) screws. No Level I, II or III evidence was available. In total, 108 patients were included. Computerized tomography combined with fluoroscopy was the most common image guidance technique used (80 patients). Where documented, there was significant improvement in mean visual analogue score (VAS) from 8.9 to 2.6. The reviewers concluded that sacroplasty with or without iliosacral screw fixation can produce significant improvements in VAS scores, however, more robust evidence is required to validate these promising early results with cement augmentation techniques.

In a retrospective case series, Whitlow et al (2007) investigated the effects of sacroplasty on pain, mobility, and activities of daily living (ADLs) and compared clinical outcomes of sacroplasty to vertebroplasty. Twelve individuals, who had failure of conservative therapy underwent percutaneous sacroplasty and 21 patients underwent percutaneous vertebroplasty for vertebral fractures. There were no statistically significant differences between the two groups at baseline. At a mean of 21 months after treatment, mean pain scores had decreased to 3 ± 1 for the sacroplasty group and 3 ±1 for the vertebroplasty group. Both procedures were associated with statistically significant decreases in pain compared with baseline; however, differences between the groups were not significant. Likewise, for measures of mobility and activities of daily living, statistically significant decreases were seen versus baseline for both procedures but differences between the sacroplasty and vertebroplasty groups were not significant. The activities assessed were dressing, bathing, transferring to a chair, transferring to a bed, walking, moving, and housework/handiwork.

At the present time, percutaneous sacroplasty is considered investigational, not medically necessary, due to insufficient evidence in the peer-reviewed literature demonstrating its safety and effectiveness. Preliminary evidence suggests that percutaneous sacroplasty may improve outcomes for patients who have sacral insufficiency fractures, however, studies have been limited to individual case series, small uncontrolled trials and small non-randomized controlled trials. Further controlled studies with long-term results are needed to confirm that percutaneous sacroplasty is a safe and effective procedure for sacral insufficiency fractures.

**Scientific Rationale**

Insufficiency fracture is a subgroup of stress fracture. Insufficiency fracture is caused by the effect of normal or physiologic stress upon weakened bone. Loss of bone trabeculae decreases the bone's elastic resistance. Sites frequently affected by insufficiency fractures are the thoracic vertebra, tibia, fibula, and calcaneus.

Sacral insufficiency fractures are often an unsuspected and undiagnosed cause of low back pain in women over the age of 55. Sacral insufficiency fractures occur when the quality of the sacral bone has become insufficient to handle the stress of weight bearing. The most common cause of sacral insufficiency fracture is osteoporosis. Other risk factors that can weaken bone include radiation to the pelvis, steroid use, and rheumatoid arthritis.
Symptoms of sacral insufficiency fracture include severe pain in the buttock, back, hip, groin, and/or pelvis, usually without a history of trauma or a history of low impact trauma. Range of motion in the low back is limited and walking is typically slow and painful. Sacral insufficiency fractures are often not seen on plain X-rays, however, the diagnosis can usually be confirmed by bone scintigraphy, magnetic resonance imaging (MRI) or computed tomography (CT).

Treatment is conservative and includes reduced weight bearing, and analgesics for pain relief. Improvement of symptoms usually begins after one to two weeks of treatment. Gradual walking with a walker or crutches is generally started once symptomatic improvement is observed. Most people are pain free in six to 12 months. The need for surgical intervention is rare.

Sacroplasty has recently been introduced as an alternative to medical management of osteoporotic sacral insufficiency fractures to provide pain relief. Performed under fluoroscopy, polymethylmethacrylate (PMMA) is percutaneously injected into the fracture site, to fill and stabilize the fracture. Sacroplasty has been proposed for those individuals with a severe decrease in functional ability and quality of life, to allow for relief of pain and return to normal activities of daily living sooner than with conservative treatment.

Peer review published literature is limited, most of which includes case reports/case series. In one small prospective study, Frey et al (2008) reported on fifty-two individuals (40 females) with sacral insufficiency fractures (SIFs) due to osteoporosis. Mean symptom duration was 34.5 days. Outcome measures included Visual Analogue Scale (VAS) score, analgesic utilization, and patient satisfaction and were performed at baseline and 30 minutes after the procedure, at 2-, 4-, 12-, 24-, and 52-week postprocedure. Analgesic usage and patient satisfaction were assessed at final follow-up. Each procedure was performed under light intravenous conscious sedation using fluoroscopy. Two bone trochars were inserted between the sacral foramen and sacroiliac joint through which 2 to 3 cc of PMMA were injected. The investigator reported that all patients were available at each follow-up interval except one patient who died because of unrelated pulmonary disease before the 4-week follow-up. The mean VAS score at baseline was 8.1 and 3.4 within 30 minutes after the procedure, 2.5 at 2, 2.1 at 4, 1.7 at 12, 1.4 at 24, and 0.8 at 52 weeks. Improvement was statistically significant using a repeated measures single-factor analysis of variance. One case of transient S1 radiculitis occurred but resolved completely with one transforaminal epidural steroid injection. The author reported that sacroplasty for SIF appears to be associated with rapid and sustained pain relief in most patients with few complications. They investigators concluded that more rigorous trials are warranted to provide definitive evidence of the safety and efficacy of sacroplasty for SIFs.

Strub et al (2007) investigated sacroplasty, using CT for needle placement and fluoroscopy to monitor the PMMA injection in 13 patients with sacral insufficiency fractures. All patients had a history of chronic back pain and had an osteoporotic sacral insufficiency fracture documented by imaging before the procedure. With the patient under conscious sedation, a bone biopsy needle was placed under CT guidance; the patient was then transferred to the fluoroscopy suite, where a PMMA mixture was injected into the sacrum under real-time fluoroscopy. Clinical outcome was assessed by telephone. A bilateral procedure was performed in 11 patients and a unilateral procedure was performed in 2 patients. An average of 4.1 mL of cement was injected for each treatment. There were no instances of cement extravasation into the central canal or sacral foramina Long-term follow-up, averaging 15 months, was available in 6 patients. Five patients (83%) reported no symptoms of pain at all.
The final patient, in whom a bilateral procedure was performed, was completely asymptomatic on the left side but reported persistent unilateral pain on the right.

Heron et al (2007) reported outcomes in three patients treated with computed tomography (CT)-guided sacroplasty as a treatment for sacral insufficiency fractures. The mean pre-procedure visual analogue score (VAS) for pain was 8 with a mean symptom duration of 8 months. The procedure was performed under CT guidance with needles being placed along the fracture lines from a posterior approach. PMMA cement was introduced in 0.2 ml aliquots after cement temperature reduction. Cement injection was monitored by four-section block axial acquisition to assess potential cement migration. The three procedures were performed without significant complication. One patient developed a tiny asymptomatic cement leak into the S1 foramen. The mean volume of cement injected into a unilateral sacral fracture was 4 ml. All patients tolerated the procedure well under intravenous sedation. The mean VAS score post-procedure was 2. Continued symptomatic relief was seen at 6 weeks and 3 months. The author concluded that CT-guided sacroplasty represents an alternative treatment for sacral insufficiency fractures that are resistant to conservative treatment.

**Review History**

- October 2008  Medical Advisory Council, initial approval
- October 2009  Update – no revisions
- October 2010  Update – no revisions. Medicare table added.
- July 2011  Update. Added Revised Medicare Table. No revisions.
- July 2012  Update. No revisions.
- May 2014  Update – no revisions

**This policy is based on the following evidence-based guidelines**


**References – Update May 2016**


**References – Update May 2015**


**References – Update May 2014**

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References – Update July 2013


References – Update July 2012


References – Update July 2011


References – Update October 2010

References – Update October 2009

References

Important Notice

General Purpose.
Health Net's National Medical Policies (the "Policies") are developed to assist Health Net in administering plan benefits and determining whether a particular procedure, drug, service or supply is medically necessary. The Policies are based upon a review of the available clinical information including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the drug or device, evidence-based guidelines of governmental bodies, and evidence-based guidelines and positions of select national health professional organizations. Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member’s contract, including medical necessity requirements. Health Net may use the Policies to determine whether under the facts and circumstances of a particular case, the proposed procedure, drug, service or supply is medically necessary. The conclusion that a procedure, drug, service or supply is medically necessary does not constitute coverage. The member’s contract defines which procedure, drug, service or supply is covered, excluded, limited, or subject to dollar caps. The policy provides for clearly written, reasonable and current criteria that have been approved by Health Net’s National Medical Advisory Council (MAC). The clinical criteria and medical policies provide guidelines for determining the medical necessity criteria for specific procedures, equipment, and services. In order to be eligible, all services must be medically necessary and otherwise defined in the member's benefits contract as described this “Important Notice” disclaimer. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member’s benefits, nor is it intended to dictate to providers how to practice medicine.

Policy Effective Date and Defined Terms.
The date of posting is not the effective date of the Policy. The Policy is effective as of the date determined by Health Net. All policies are subject to applicable legal and regulatory mandates and requirements for prior notification. If there is a discrepancy between the policy effective date and legal mandates and regulatory requirements, the requirements of law and regulation shall govern. * In some states, prior notice or posting on the website is required before a policy is deemed effective. For information regarding the effective dates of Policies, contact your provider representative. The Policies do not include definitions. All terms are defined by Health Net. For information regarding the definitions of terms used in the Policies, contact your provider representative.

Policy Amendment without Notice.
Health Net reserves the right to amend the Policies without notice to providers or Members. In some states, prior notice or website posting is required before an amendment is deemed effective.

No Medical Advice.
The Policies do not constitute medical advice. Health Net does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

No Authorization or Guarantee of Coverage.
The Policies do not constitute authorization or guarantee of coverage of particular procedure, drug, service or supply. Members and providers should refer to the Member contract to determine if exclusions, limitations, and dollar caps apply to a particular procedure, drug, service or supply.

**Policy Limitation: Member’s Contract Controls Coverage Determinations.**
Statutory Notice to Members: The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. The determination of coverage for a particular procedure, drug, service or supply is not based upon the Policies, but rather is subject to the facts of the individual clinical case, terms and conditions of the member’s contract, and requirements of applicable laws and regulations. The contract language contains specific terms and conditions, including pre-existing conditions, limitations, exclusions, benefit maximums, eligibility, and other relevant terms and conditions of coverage. In the event the Member’s contract (also known as the benefit contract, coverage document, or evidence of coverage) conflicts with the Policies, the Member’s contract shall govern. The Policies do not replace or amend the Member’s contract.

**Policy Limitation: Legal and Regulatory Mandates and Requirements**
The determinations of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern.

**Reconstructive Surgery**
CA Health and Safety Code 1367.63 requires health care service plans to cover reconstructive surgery. “Reconstructive surgery” means surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do either of the following:

1. To improve function or
2. To create a normal appearance, to the extent possible.

Reconstructive surgery does not mean "cosmetic surgery," which is surgery performed to alter or reshape normal structures of the body in order to improve appearance.

Requests for reconstructive surgery may be denied, if the proposed procedure offers only a minimal improvement in the appearance of the enrollee, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery.

**Reconstructive Surgery after Mastectomy**
California Health and Safety Code 1367.6 requires treatment for breast cancer to cover prosthetic devices or reconstructive surgery to restore and achieve symmetry for the patient incident to a mastectomy. Coverage for prosthetic devices and reconstructive surgery shall be subject to the co-payment, or deductible and coinsurance conditions, that are applicable to the mastectomy and all other terms and conditions applicable to other benefits. "Mastectomy” means the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician and surgeon.

**Policy Limitations: Medicare and Medicaid**
Policies specifically developed to assist Health Net in administering Medicare or Medicaid plan benefits and determining coverage for a particular procedure, drug, service or supply for Medicare or Medicaid members shall not be construed to apply to any other Health Net plans and members. The Policies shall not be interpreted to limit the benefits afforded Medicare and Medicaid members by law and regulation.