See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Magnetic resonance-guided focused ultrasound (MRgFUS) is considered investigational and is not covered for palliative treatment of bone metastases.

Link to Policy Summary

BILLING GUIDELINES

There are no specific CPT codes for the use of magnetic resonance–guided focused ultrasound ablation in specific cancers. Therefore, an unlisted code would be used based on the anatomic location of the metastasis being treated (e.g., 23929 for the clavicle) or perhaps one of the radiation oncology unlisted codes (e.g., 77299 or 77499).
CPT/HCPCS CODES

The HCPCS code C9734 is not specific to the indications in this policy. However, when requested for palliative treatment of bone metastases, this code is considered investigational.

All Lines of Business

Prior Authorization Required

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9734</td>
<td>Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance</td>
</tr>
</tbody>
</table>

Unlisted Codes

All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be denied as **Not Covered**.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20999</td>
<td>Unlisted procedure, musculoskeletal system</td>
</tr>
<tr>
<td>76498</td>
<td>Unlisted magnetic resonance procedure (eg, diagnostic, interventional)</td>
</tr>
<tr>
<td>76999</td>
<td>Unlisted ultrasound procedure (eg, diagnostic, interventional)</td>
</tr>
<tr>
<td>77299</td>
<td>Unlisted procedure, therapeutic radiology clinical treatment planning</td>
</tr>
<tr>
<td>77499</td>
<td>Unlisted procedure, therapeutic radiology treatment management</td>
</tr>
</tbody>
</table>

DESCRIPTION

A large percentage of cancers develop tumor metastases to the skeleton. Currently available treatments for palliation of pain from bone metastases include external beam radiation therapy (EBRT); chemotherapy; bisphosphonates; radiopharmaceuticals; laser ablation; radiofrequency ablation (RFA); hormonal therapy; surgery; cryotherapy; and analgesic medications (e.g. narcotics and nonsteroidal anti-inflammatory drugs). However, each of these options has its own potential for side effects and intolerability. Therefore, additional options to treat bone metastases that would potentially allow for repeated and unlimited treatments with minimal side effects are needed.¹

High-intensity focused ultrasound (HIFU) treatment paired with magnetic resonance imaging guidance (MRgFUS) is being investigated as a non-invasive pain relief strategy for painful bone metastases that are refractory to medical therapies and do not respond to radiation therapy. The sole device with approval from the Food & Drug Administration (FDA) for this indication is the ExAblate system (InSightec Ltd.).²

According to Hayes, the ExAblate system “uses a focused ultrasound transducer is used via a robotic system within a patient table, all of which is fully integrated within an MRI scanner. A physician controls and monitors the treatment while using the MRI to identify, target, and deliver HIFU to the bone metastases.”¹
REVIEW OF EVIDENCE

Evaluating the safety and effectiveness of magnetic resonance–guided focused ultrasound (MRgFUS) treatment with FDA-approved devices requires randomized controlled trials to isolate the treatment effect of MRgFUS. Randomization is critical in evaluating any intervention in which outcomes reported are subjective and self-reported clinically such as pain and function, as these outcomes may be influenced by nonspecific effects like placebo response and the natural history of the disease. As a result, when randomization is used, differences in reported outcomes between treatment groups may be attributed to the treatment in question. In addition, randomized studies must be sufficiently powered in order to eliminate any spurious results due to chance, must be evaluated in general groups of patients to allow generalizability of results, and must be evaluated against the existing standard of care for the condition being treated.

Therefore, the evidence review below has focused on randomized controlled trials (RCTs) and systematic reviews assessing the safety and efficacy of MRgFUS compared with other treatments currently being used for alleviation of pain due to bone cancer metastasis. A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of MRgFUS as a treatment for bone metastases. Below is a summary of the available systematic reviews and RCTs identified through July of 2018.

In 2016 Hayes published a systematic review of MRgFUS therapy (ExAblate; InSightec Ltd.) for MRgFUS for palliative treatment of metastatic bone pain in adult patients who are refractory to, have refused, or are not suitable candidates for standard palliative treatments. The review included three studies (two case series and one RCT). The update published in 2018 also included one small nonrandomized study comparing MRgFUS (n=21) to standard conventional radiation therapy (n=42), and two small pretest/posttest studies (n=20-23). Overall, the body of evidence was considered to be of very-low-quality with limited applicability in the clinical setting. The quality of individual included studies was deemed low, with all studies lacking precision, directness, and consistency of data. According to Hayes: “the studies had significant limitations, including limited follow-up, small sample sizes, a lack of active comparators, and a lack of randomization in the pretest-posttest studies. Additional limitations included statistically significant differences between study groups and a lack of power analyses.” As a result, Hayes rated the use of MRgFUS for palliation of metastatic bone pain as “D2”.

To date, only one RCT was identified that evaluated the safety and efficacy of MRgFUS treatment for bone cancer metastases. This RCT was included in the Hayes review above. This moderately-sized RCT, published in 2014, randomized patients with painful bone metastases who were unsuitable for or declined radiotherapy into two groups: active (n=112) or sham (n=35). At 3-month follow-up, a large percentage of patients in both the active group (26 patients, 23%) and sham group (23 patients, 66%) had dropped out of the trial and were unavailable for follow-up. This trial was limited by the use of a composite primary outcome measure, short-term follow-up, small size of the sham group, and high attrition rate. Since a large number of sham patients (66%) did not complete the three-month follow-up; the results reported regarding treatment efficacy must be interpreted with caution as the sham group was likely underpowered. Additional randomized studies of larger size and longer follow-up are required.
to isolate the treatment effect of MRgFUS and the length of symptom relief in patients with bone metastases.

No additional studies were identified since the 2018 update of the Hayes review.

CLINICAL PRACTICE GUIDELINES

National Comprehensive Cancer Network (NCCN)

The 2018 NCCN adult cancer pain guidelines\(^4\) state the following regarding management of bone pain:

- “Ablative strategies such as radiofrequency ablation (RF) or ultrasound (US) ablation may be performed to reduce pain and prevent skeletal-related events (SREs).”

NCCN notes that, “several small studies have also demonstrated the palliative effects of HIFU treatment of bone lesions,” citing three small case series (n=18-31 patients) which evaluated the use of MRgFUS.

CENTERS FOR MEDICARE & MEDICAID

As of 08/02/2018, no Centers for Medicare & Medicaid (CMS) coverage guidance was identified which addresses magnetic resonance-guided focused ultrasound (MRgFUS) for palliative treatment of bone metastases.

POLICY SUMMARY

There is insufficient evidence that magnetic resonance-guided focused ultrasound (MRgFUS) as a treatment for palliation of pain due to bone cancer is safe or effective. In addition, current clinical practice guidelines, including the National Comprehensive Cancer Network (NCCN), do not strongly support the use of this treatment over other treatments for cancer-related bone pain.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.
REGULATORY STATUS

U.S. Food & Drug Administration (FDA)

In 2012, the ExAblate® System (Models 2000/2100/2100 VI) (InSightec, Inc.), extended its FDA indications to include for pain palliation of metastatic bone cancer. These devices have been approved through the PMA process and are intended in patients 18 years of age or older who are suffering from bone pain due to metastatic disease and who are failures of standard radiation therapy, or not candidates for, or refused radiation therapy.

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

REFERENCES

1. Hayes. Health Technology Brief. Magnetic Resonance–Guided Focused Ultrasound Therapy (ExAblate; InSightec Ltd.) for Palliation of Painful Bone Metastases. Published: 03/03/2016. Updated: 03/19/2018. https://www.hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=15732&searchStore=%24search_type%3Dphrase%24icd%3D%24keywords%3DMagnetic%20Resonance%20Guided%20Focused%20Ultrasound%20Therapy%24status%3DAll%24page%3D1%24from_date%3D%24to_date%3D%24report_type_options%3D%24technology_type_options%3D%24organ_system_options%3D%24specialty_options%3D%24order%3DsearchRelevance. Accessed 08/02/2018.