MEDICAL POLICY	Ganglion Impar Blocks
Effective Date: 3/1/2021  3/1/2021 Medical Officer Date	Medical Policy Number: 104 Technology Assessment Committee Approved Date: 8/13; 7/14; 6/15; 3/16; 4/17 Medical Policy Committee Approved Date: 10/17; 12/18; 2/19; 2/2020; 2/2021

See Policy CPT 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

Ganglion impar blocks are considered **investigational and are not covered** as a treatment of any condition, including but not limited to:

- Perineal pain, with or without malignancy
- Perineal pain, with or without malignancy
- Rectal/Anal pain (proctitis)
- Distal urethral pain
- Vulvodynia
- Scrotal pain
- Female pelvic/vaginal pain
- Complex Regional Pain Syndrome
- Endometriosis
- Vaginal protrusion
- Chronic prostatitis

- Failed Back Surgery Syndrome (FBSS)
- Proctalgia Fugax
- Post-surgical thrombosis of the perineal veins
- Coccygodynia
- Radiation proctitis
- Postherpetic neuralgia
- Burning and localized perineal pain associated with urgency

Link to Policy Summary

BILLING GUIDELINES

According to the American Medical Association CPT Assistant[1], the unlisted code 64999 should be used for ganglion impar blocks. Therefore, other codes, such as 64520 and 64450, are considered inappropriate and should not be used to bill for this service.

CPT CODES

All Lines of Business

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.**

64999	Unlisted procedure, nervous system

DESCRIPTION

The ganglion impar (also known as the ganglion of Walther) is a single, small, sympathetic ganglion located in the retrorectal space, anterior to the sacrococcygeal joint or coccyx. It provides the nociceptive and sympathetic supply to the perineal structure. Blockade of this structure is proposed as a treatment option for chronic perineal, rectal, pelvic, and visceral pain, including rectal/perineal cancer pain.

Ganglion impar block is one of several interventional techniques used to treat chronic pain of various etiologies. In the case of coccydynia (also known as coccygodynia), a number of different interventional procedures are considered, including: injections around the coccyx (sacrococcygeal junction or around the sacrococcygeal ligaments), caudal epidural steroid injections, radiofrequency ablation, spinal cord stimulation, and ganglion impar blocks. Although some specialists advocate the use of interventional procedures in a cases of chronic pain due to coccygodynia, there is no clear consensus on the best site of injection.[2]

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of ganglion impar block as a treatment for pain. Below is a summary of the available evidence identified through December 2020.

Systematic reviews

In 2018, reviewed in 2020, Hayes published a health technology assessment on ganglion impar block (GIB) or radiofrequency thermocoagulation (RFT) for the treatment of chronic coccydynia.[3] Seven noncomparative studies evaluating patients with coccydynia were included in the analysis. Four studies measured pain intensity after treatment with GIB, using either visual analog scale (VAS) or numeric rating scale (NRS) scores. The studies suggested a statistically significant improvement in pain intensity (≥ 30%) from all endpoint after initial GI, including neuropathic pain, measured in one study. Three studies measured treatment success, defined as ≥ 50% improvement in pain intensity in 2 studies and absence of neuropathic pain in one study. Treatment success occurred in 71% to 86% of participants. Other measures included physical functioning (in one study), quality of life and depressive symptoms (in one study), and procedural success (in 2 studies).

Hayes found that there was insufficient evidence to draw definitive conclusions regarding the efficacy of GIB for chronic coccydynia. Individual studies were found to be of poor quality, lacking comparator groups, randomization, adequate sample sizes, power analyses, and important patient-centered outcome measures. Hayes gave a D2 rating for use of GIB for the treatment of coccydynia in adults.

Nonrandomized Studies

- In 2007, Toshniwal analyzed the feasibility, safety, and efficacy of ganglion impar block by transsacrococcygeal approach in a small prospective case series, including 16 consecutive patients with chronic perineal pain (CPP) due to varying etiologies including cancer pain.[4] Five patients were treated with one or more therapeutic blocks with methylprednisolone with bupivacaine, while the remaining 11 patients were treated with neurolytic block with phenol. At two months follow-up, all blocks were reported to be effective (minimum of 50% reduction in pain by VAS score). No adverse events were reported. All the patients had significant pain relief during two month follow-up ($p < 0.05$ compared to baseline).

- In 2009, Agarwal-Kozlowski et al. reported results from a retrospective review of charts and computed tomography (CT)-scans of patients who underwent block and neuroablation of the ganglion impar between 2003 and 2007.[5] Interventional pain therapy by ganglion impar block was performed in 43 patients presenting with perineal pain due to varying etiologies; including of unknown origin (n=15), carcinoma of the prostate (n=8), colorectal carcinoma (n=7), post-surgery of thrombosis of perineal veins (n=3), post-herpetic neuralgia (n=4), malformation of the spinal cord (n=2), vaginal protrusion (n=2), failed back surgery syndrome (n=1), and ablation of testis (n=1). CT-guided block was not associated with any adverse events and resulted in a significant reduction of pain post-intervention (VAS score pre-treatment 8.2±1.6 to post-treatment 2.2±1.6; $p<0.0001$, 95% confidence interval [CI]: 0.5) immediately at discharge and to 2.2±1.4 ($p<0.0001$, 95% CI: 0.4) at four months follow up.

- In 2010, Datir et al. published the results of a small case series that evaluated the efficacy of CT-guided ganglion impar blocks in the management of coccydynia, including 8 patients with coccydynia secondary to trauma or unknown cause who had failed conservative treatments.[6] The authors reported a technical success of 100% and no complications. At six months follow-up three patients (37%) had complete relief of pain, three (37%), had partial relief and were given a second injection at three months. At the end of the 6-month follow-up period, six patients (75%) experienced symptomatic relief (four complete relief and two partial relief) without any additional resort to conventional pain management. Two patients (25%) did not have any symptomatic improvement.

- In 2011, Sáenz et al. reported the results of a small retrospective case series of 23 patients with coccydynia who had failed to respond to conservative management.[7] Patients were treated by radiologically guided ganglion blockade impar and/or caudal blockade with 1% lidocaine 60–80 mg triamcinolone. Of these 23 patients, 21 were available for clinical review and completed a questionnaire. Sixteen patients with coccydynia due to trauma reported marked improvement in pain post-procedure. Five patients reported moderate or poor improvement, although none described worsening of pain at follow-up. None of the patients reported complications.

- In 2015, Gunduz et al. reported on a retrospective pilot study evaluating results and follow up of 34 ganglion impar blocks in 22 patients with coccygodynia who did not respond to conservative treatment.[8] For achieving at least 50% relief of pain, reported by VAS scores, the success rate of a first injection was 82%. In patients treated successfully, relief lasted for a median duration of six months. Nine patients who presented for repeat treatment reported pain relief for a median period of 17 months. No relief was achieved in two of these patients when they presented for a third treatment. The authors concluded ganglion impar blocks appear to be effective in patients who have coccygodynia resistant to conservative therapy, but controlled studies are required to elucidate the mechanism of this effect.

- In 2017, Le Clerc et al. published the results of a retrospective single-center study that evaluated the effectiveness of three repeated ganglion impar blocks in patients with chronic pelvic and perineal pain of various etiologies, including 83 patients (220 blocks).[9] With each repeated block, 10% or more of the cohort was lost to follow-up. For the intent-to-treat analysis, 62 (74.7%) of the patients received three CT-guided ganglion impar blocks with ropivacaine and were available for analysis. Of the 220 blocks performed, 193 (87.7%) were considered to be technically effective, with transient improvement of pain by more than 50% immediately after the first treatment and complete but transient pain relief one hour after the procedure in 119 (54.1%) procedures. Analysis of the Patient Global Impression of Change (PGI-C), a self-reported measure of long-term efficacy, one month after the block demonstrated improvement in 41% of cases in the overall population and in 43.6% of cases in the subgroup of 62 patients treated by three blocks. However, 8.4% of patients reported worse symptoms and 50.6% reported no long-term change. The authors note that long-term efficacy of this technique is a limitation, and that longer-acting mechanisms, such as neuromodulation, must be studied.

- Validity of positive findings from other, recent studies[10-14] is undermined by either limitations in study designs, small sample sizes, inadequate follow-up and/or a lack of controls.

CLINICAL PRACTICE GUIDELINES

National Comprehensive Cancer Network (NCCN)

The NCCN Adult Cancer Pain-Version 1.2020 guidelines recommended the use of ganglion impar block as one of many options to treat rectal/perineal pain for well-localized pain syndromes.[15] The guideline recommended ganglion impar blocks be considered if it was determined that an interventional approach is appropriate, and the pain site evaluated and determined that the "technique will provide sufficient benefit." No evidence was cited in support this recommendation.

POLICY SUMMARY

There is insufficient evidence that ganglion impar blocks lead to significant long-term pain reduction for patients with for chronic perineal, rectal, pelvic, or visceral pain. In addition, no studies were identified that compare the safety or efficacy of ganglion impar block to other interventional procedures for chronic pain of any etiology. Lastly, NCCN guidelines recommend ganglion impar block as one of a many options to treat rectal/perineal pain for well-localized pain syndromes; however, NCCN does not cite any studies to support this recommendation. No evidence-based clinical practice guidelines were identified which recommend the use of ganglion impar block as a treatment of any condition.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

As of 12/29/2020, no Centers for Medicare & Medicaid (CMS) coverage guidance was identified which addresses ganglion impar blocks.

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

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. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously

considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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