# **Medical Policy**

## **Ganglion Impar Blocks**

### **MEDICAL POLICY NUMBER: 104**

Effective Date: 1/1/2024	COVERAGE CRITERIA	2
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**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 Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. 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. 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.

**SCOPE:** Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

### PLAN PRODUCT AND BENEFIT APPLICATION

Commercial

Medicaid/OHP\*

Medicare\*\*

### \*Medicaid/OHP 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.

See Guideline Notes 172 and 173 of the OHP Prioritized List of Health Services for guidance on New and Emerging Technology. In the absence of OHP guidance, PHA will follow this policy.

### \*\*Medicare Members

This <u>Company</u> policy may be applied to Medicare Plan members only when directed by a separate <u>Medicare</u> policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

### **COVERAGE CRITERIA**

- I. Ganglion impar blocks may be considered **medically necessary** for the treatment of rectal/perineal pain for well-localized pain syndromes associated with adult cancer pain.
- II. Ganglion impar blocks are considered **not medically necessary** for all other indications, including but not limited to:
  - A. Rectal/perineal pain not associated with cancer
  - B. Distal urethral pain
  - C. Vulvodynia
  - D. Scrotal pain
  - E. Female pelvic/vaginal pain
  - F. Complex Regional Pain Syndrome
  - G. Endometriosis
  - H. Vaginal protrusion
  - I. Chronic prostatitis
  - J. Failed Back Surgery Syndrome (FBSS)
  - K. Proctalgia Fugax
  - L. Post-surgical thrombosis of the perineal veins
  - M. Coccygodynia
  - N. Postherpetic neuralgia
  - O. Burning and localized perineal pain associated with urgency

### **POLICY CROSS REFERENCES**

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

### **POLICY GUIDELINES**

#### BACKGROUND

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.<sup>1</sup>

### **REGULATORY STATUS**

#### **U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

### CLINICAL EVIDENCE AND LITERATURE REVIEW

#### **EVIDENCE REVIEW**

#### Systematic reviews

Originally in 2018 and updated in 2023, Hayes published a health technology assessment on ganglion impar block (GIB) or radiofrequency thermocoagulation (RFT) for the treatment of chronic coccydynia.<sup>2</sup> Nine studies (N= 29-73) evaluating patients with coccydynia were included in the analysis including three randomized trials of GIB; one prospective repeated measures time series study of GIB; one retrospective, repeated measures timeseries study of GIB; two retrospective comparative repeated measures time series studies that evaluated GIB relative to RFT; and two retrospective repeated measures time series studies of RFT. Two of the studies were completed in India and seven were completed in Turkey. Pain intensity (7 studies), treatment success (2 studies), presence/absence of neuropathic pain (1 study), patient satisfaction (2 studies), physical functioning/disability (2 studies), depression (1 study), quality of life (1 study) and complications (6 studies) were reviewed as outcomes. Across studies there was consistent and statistically significant evidence of moderate to substantial reduction in pain intensity for up to 3 months after treatment with GIB (reduction in pain of 39%-87%). After the three months, changes in pain intensity were more modest. Pain intensity was assessed using a numeric rating scale (NRS) (6 studies) or visual analog scale (VAS) (1 study) with an improvement in pain intensity of  $\geq$  30% being considered clinically significant and an improvement of  $\geq$  indicating substantial improvement. The low-quality rating of the body of evidence mainly stems from the small number of comparative studies, small sample sizes, and the quality of the individual studies, which ranged from fair to poor. Hayes gave ganglion impar block a "C" evidence level for the treatment of chronic coccydynia in adults. The authors state "this rating reflects a low-quality body of evidence suggesting potential benefit and minimal harms of GIB for the treatment of chronic coccydynia. However, substantial uncertainty exists due to limited evidence on functional and quality-of-life (QOL) outcomes, limited follow-up periods, and concerns regarding individual study limitations."

#### **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.<sup>3</sup> 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).</li>
- 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.<sup>4</sup> Interventional pain therapy by ganglion impar block was performed in 43 patients presenting with perineal pain due to varying etiologies; including Page 4 of 8

of unknown origin (n=15), carcinoma of the prostate (n=8), colorectal carcinoma (n=7), postsurgery 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 posttreatment 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.<sup>5</sup> 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.<sup>6</sup> 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.<sup>7</sup> 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).<sup>8</sup> 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

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(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<sup>9-13</sup> 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 2.2023 guidelines recommended the use of ganglion impar block as one of many options to treat rectal/perineal pain for well-localized pain syndromes.<sup>14</sup> 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.

#### **EVIDENCE SUMMARY**

National Comprehensive Cancer Network guidelines recommend ganglion impar block as one of many options to treat rectal/perineal pain for well-localized pain syndromes associated with adult cancer pain.

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.

No other evidence-based clinical practice guidelines were identified which recommend the use of ganglion impar block as a treatment of any condition.

### BILLING GUIDELINES AND CODING

According to the American Medical Association CPT Assistant<sup>15</sup>, 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.

CODES*		
СРТ	64999	Unlisted procedure, nervous system

\*Coding Notes:

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- See the non-covered and prior authorization lists on the Company <u>Medical Policy, Reimbursement Policy</u>, <u>Pharmacy Policy and Provider Information website</u> for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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### **POLICY REVISION HISTORY**

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
1/2024	Annual review. Update noncoverage position from investigational to NMN when medical necessity criteria are not met