Coding and Reimbursement for Intrathecal Therapy

The material referenced and provided is based upon research of current Medicare reference sources. The final decision of billing for any product or procedure must be made by the provider of care considering the medical necessity of the services and supplies provided, the regulations of insurance carriers, and any local, state, or federal laws that apply to the supplies and services rendered. We are providing you this information in an educational capacity with the understanding that we are not engaged in rendering legal, accounting, or other professional services.

IMPORTANT RISK INFORMATION

WARNING: DO NOT DISCONTINUE ABRUPTLY

See full prescribing information for complete boxed warning.

Abrupt discontinuation of intrathecal baclofen, regardless of the cause, has resulted in sequelae that include high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity, that in rare cases has advanced to rhabdomyolysis, multiple organ-system failure and death.

Prevention of abrupt discontinuation of intrathecal baclofen requires careful attention to programming and monitoring of the infusion system, refill scheduling and procedures, and pump alarms. Patients and caregivers should be advised of the importance of keeping scheduled refill visits and should be educated on the early symptoms of baclofen withdrawal. Special attention should be given to patients at apparent risk (e.g. spinal cord injuries at T-6 or above, communication difficulties, history of withdrawal symptoms from oral or intrathecal baclofen). Consult the technical manual of the implantable infusion system for additional post-implant clinician and patient information.

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MEDICARE PAYMENT INFORMATION

Code*	Description	Medicare payment as of 1/5/2023 [1,2†] Unadjusted for Geography‡		
		Hospital Outpatient Payment	Physician Payment: Facility	Physician Payment: Nonfacility or Office
TRIAL DOSE AND PROCEDURES				
J0476	Injection, baclofen, 50 mcg for intrathecal trial	Updated quarterly, most current information can be downloaded from CMS website[3]		
62322	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance	Assigned to APC 5443 with payment of $852.18	$80.65	$140.29
62323	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT)	Assigned to APC 5442 with payment of $644.34	$98.95	$262.29
REFILL ANALYSIS REPROGRAMMING				
62369	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status): with reprogrammable and refill	Assigned to APC 5743 with payment of $276.65	$34.90	$93.19
62370	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status): with reprogrammable and refill (requiring skill of a physician or other qualified healthcare professional)	Assigned to APC 5743 with payment of $276.65	$46.09	$93.87
95990	Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular), includes electronic analysis of pump when performed	Assigned to APC 5694 with payment of $332.62	$90.82	$90.82
95991	Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular), includes electronic analysis of pump when performed, requiring skill of a physician or other qualified healthcare professional	Assigned to APC 5441 with payment of $271.89	$40.33	$111.83

Code*	Description	Average Sales Price Payment Allowance Limits
J0475	Injection, baclofen, 10 mg	Updated quarterly, most current information can be downloaded from CMS website[3]
J2274	Injection, morphine sulfate, preservative-free for epidural or intrathecal use, 10mg	Updated quarterly, most current information can be downloaded from CMS website[3]

Check with the local Medicare contractor or other payers for coding and billing instructions for the KD modifier for "drug or biological infused through DME" as it relates to an implanted pump.

GABLOFEN® (BACLOFEN INJECTION) PREFILLED SYRINGE

NDC #	Description	Size	Billing Units
66794-151-01	50 mcg per mL	1 mL Syringe - 50 mcg per 1 mL	
66794-155-01	500 mcg per mL	20 mL Syringe - 10,000 mcg per 20 mL	1
66794-156-01	1,000 mcg per mL	20 mL Syringe - 20,000 mcg per 20 mL	2
66794-157-01	2,000 mcg per mL	20 mL Syringe - 40,000 mcg per 20 mL	4

GABLOFEN® (BACLOFEN INJECTION) VIAL

NDC #	Description	Size	Billing Units
66794-155-02	500 mcg per mL	20 mL Vial - 10,000 mcg per 20 mL	1
66794-156-02	1,000 mcg per mL	20 mL Vial - 20,000 mcg per 20 mL	2
66794-157-02	2,000 mcg per mL	20 mL Vial - 40,000 mcg per 20 mL	4

MITIGO (MORPHINE SULFATE INJECTION USP) VIAL

NDC #	Description	Size	Billing Units
66794-160-02	10mg/mL	20 mL Vial -200mg per 20 mL	20
66794-162-02	25mg/mL	20 mL Vial -500mg per 20mL	50

FOR REIMBURSEMENT QUESTIONS, PLEASE CONTACT 1-844-529-8995

†Please refer to CMS.gov for changes in Medicare payments.
‡Actual Medicare allowables vary by region of the country.

References:
1 https://www.cms.gov/apps/physician-fee-schedule/overview.aspx. Last accessed: January 19, 2023
2 MediRegs - accessed January 2023
3 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html. Last accessed: January 19, 2023

INDICATIONS AND USAGE FOR GABLOFEN® (baclofen Injection)

- Gablofen® (baclofen injection) is a gamma-aminobutyric acid (GABA) ergic agonist indicated for use in the management of severe spasticity of cerebral or spinal origin in adult and pediatric patients age 4 years and above.
- Gablofen should be reserved for patients unresponsive to oral baclofen therapy, or those who experience intolerable central nervous system side effects at effective doses.
- Patients should first respond to a screening dose of intrathecal baclofen prior to consideration for long term infusion via an implantable pump.
- Spasticity due to traumatic brain injury: wait at least one year after injury before considering Gablofen therapy.

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Prevention of abrupt discontinuation of intrathecal baclofen requires careful attention to programming and monitoring of the infusion system, refill scheduling and procedures, and pump alarms. Patients and caregivers should be advised of the importance of keeping scheduled refill visits and should be educated on the early symptoms of baclofen withdrawal. Special attention should be given to patients at apparent risk (e.g. spinal cord injuries at T-6 or above, communication difficulties, history of withdrawal symptoms from oral or intrathecal baclofen). Consult the technical manual of the implantable infusion system for additional post-implant clinician and patient information.

CONTRAINDICATIONS

- Hypersensitivity to baclofen.
- Do not use Gablofen for intravenous, intramuscular, subcutaneous or epidural administration.

WARNINGS AND PRECAUTIONS

- Risk of life-threatening overdose during pump refills. Use extreme caution when filling the Medtronic SynchroMed® II Programmable Pump which is equipped with an injection port that allows direct access to the intrathecal catheter. Direct injection into the catheter through the catheter access port may cause a life-threatening overdose.
- Use only with Medtronic SynchroMed® II Programmable Pump (or other pumps labeled for intrathecal administration of Gablofen (baclofen injection)).
- Potential for contamination due to non-sterile external surface of prefilled syringe. Although the drug solution and pathway in the Gablofen prefilled syringes are sterile, the external surface of the prefilled syringes (all strengths, including the 50 mcg/mL strength) are non-sterile and have the potential to lead to contamination and consequent adverse reactions. The use of Gablofen prefilled syringe in an aseptic setting (e.g., operating room) to fill sterile intrathecal pumps prior to implantation in patients is not recommended, unless the external surface of the prefilled syringe is treated to ensure sterility. Gablofen supplied in vials may be used with conventional aseptic technique to fill intrathecal pumps prior to implantation.
- Resuscitative equipment and trained staff must be available during screening dose, dose titration, and refills due to the potential life-threatening CNS depression, cardiovascular collapse, and/or respiratory failure.
- Overdose may cause drowsiness, lightheadedness, dizziness, somnolence, respiratory depression, seizures, rostral progression of hypotonia and loss of consciousness progressing to coma.
- Use with caution in patients with psychotic disorders, schizophrenia or confusional states as it may exacerbate condition(s).
- Fatalities have been reported with intrathecal baclofen use.
- Caution should be used in patients with a history of autonomic dysreflexia.
- Presence of infection may increase the risk of surgical complication and complicate dosing of Gablofen.
- May cause drowsiness: use caution in operation of automobiles, dangerous machinery and activity that may be hazardous by decreased alertness. Other CNS depressants and alcohol may add to this effect.
- Potential development of intrathecal mass formation. Clinicians should monitor for signs and symptoms of new neurologic symptoms including the use of imaging diagnostic modalities.
- Oral baclofen use has been associated with a dose-related increase in incidence of ovarian cysts.

ADVERSE REACTIONS

SERIOUS ADVERSE REACTIONS

- Sudden withdrawal of Gablofen can result in serious complications that include high fever, confusion, muscle stiffness, multiple organ-system failure, and death. Inform patients that early symptoms of Gablofen withdrawal may include increased spasticity, itching, and tingling of extremities. If Gablofen withdrawal or a pump malfunction is suspected, patients should be brought immediately to a hospital for assessment and treatment.
- Gablofen overdose may occur suddenly or insidiously, and symptoms may include confusion, drowsiness, lightheadedness, dizziness, slow or shallow breathing, seizures, loss of muscle tone, loss of consciousness, and coma.
- Other serious adverse events may include: potential development of intrathecal mass formation, drainage, infection, meningitis, unmanageable trunk control, CSF leakage, coma and death.

COMMON ADVERSE REACTIONS

- The most common adverse reactions in patients with spasticity of spinal origin were hypotonia (25.3%), somnolence (20.9%), dizziness, nausea/vomiting, hypotension, headache, and convulsions.
- The most common adverse reactions in patients with spasticity of cerebral origin were hypotonia (34.7%), somnolence (18.7%), headache (10.7%), agitation, constipation, leukocytosis, chills, and urinary retention.
- Other common adverse events may include hypoventilation, hypertonia, paresthesia, increased salivation, back pain, pruritus, diarrhea, peripheral edema, asthenia, pain, confusion, speech disorder, amblyopia, accidental injury, and dry mouth.

USE IN SPECIFIC POPULATIONS

- Pregnancy Category C. The effect of baclofen in labor and delivery is unknown.
- Breastfeeding: Baclofen is excreted into breast milk at oral therapeutic doses.
- Pediatric use: Safety and effectiveness in pediatric patients below the age of 4 years have not been established.

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INDICATIONS AND USAGE FOR MITIGO (Morphine Sulfate Injection, USP – Preservative-free)

MITIGO (Morphine Sulfate Injection, USP – Preservative-free) is an opioid agonist for use in continuous microinfusion devices and indicated only for intrathecal or epidural infusion in the management of intractable chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

IMPORTANT RISK INFORMATION

WARNING: RISKS WITH NEURAXIAL ADMINISTRATION; LIFE-THREATENING RESPIRATORY DEPRESSION; RISK OF ADDICTION, ABUSE, AND MISUSE; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

See full prescribing information for complete boxed warning.

- Single-dose neuraxial administration may result in acute or delayed respiratory depression up to 24 hours. Because of the risk of severe adverse reactions when MITIGO is administered by the epidural or intrathecal route of administration, patients must be observed in a fully equipped and staffed environment for at least 24 hours after the initial dose.
- Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase. Patients must be observed in a fully equipped and staffed environment for at least 24 hours after each test dose and, as indicated, for the first several days after surgery.
- MITIGO exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess patient's risk before prescribing and monitor regularly for these behaviors and conditions.
- Prolonged use of MITIGO during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. If prolonged opioid use is required in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.
- Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation.

CONTRAINDICATIONS

- Significant respiratory depression
- Acute or severe bronchial asthma in an unmonitored setting in absence of resuscitative equipment
- Concurrent use of monoamine oxidase inhibitors (MAOIs) or use of MAOIs within the last 14 days
- Known or suspected gastrointestinal obstruction, including paralytic ileus
- Hypersensitivity or intolerance to morphine

Neuraxial administration of MITIGO is contraindicated in patients with:

- Infection at the injection microinfusion site
- Concomitant anticoagulant therapy
- Uncontrolled bleeding diathesis

The presence of any other concomitant therapy or medical condition which would render epidural or intrathecal administration of medication especially hazardous

WARNINGS AND PRECAUTIONS

- Risk of Inflammatory Masses: Monitor patients receiving continuous infusion of MITIGO via indwelling intrathecal catheter for new signs or symptoms of neurologic impairment.
- Risk of Tolerance and Myoclonic Activity: Monitor patients for unusual acceleration of neuraxial morphine requirements, which may cause myoclonic-like spasm of lower extremities. Detoxification may be required.
- Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients: Monitor closely, particularly during initiation and titration.
- Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid.
- Severe Hypotension: Monitor during dosage initiation and titration. Avoid use of MITIGO in patients with circulatory shock.
- Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness: Monitor for sedation and respiratory depression. Avoid use of MITIGO in patients with impaired consciousness or coma.

ADVERSE REACTIONS

Most serious adverse reactions were respiratory depression, apnea, circulatory depression, respiratory arrest, shock, and cardiac arrest. Other common frequently observed adverse reactions include: sedation, lightheadedness, dizziness, nausea, vomiting, and constipation.

USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause fetal harm.
- Hepatic and Renal Impairment: May affect the metabolism and excretion of MITIGO.

For questions regarding Adverse Events, Product Monitoring, and Medical Inquiries for Gablofen® (baclofen injection) and MITIGO™ (morphine sulfate injection, USP-Preservative-free), please call 888.525.8114 or email Global Medical Information at medical.information@piramal.com. You may also report this information to the FDA's MedWatch Reporting System by phone at 1.800.FDA.1088, by facsimile at 1.800.FDA.0178, or by mail using Form 3500 available at www.fda.gov/medwatch.

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