Gablofen®
(baclofen injection)

# Coding and Reimbursement for Gablofen®

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 1/1/2018 [1,2†] Unadjusted for Geography [‡] | | |
|---|---|---|---|---|
| | | Hospital Outpatient Payment | Physician Payment: Facility | Physician Payment: Nonfacility or Office |
| **TRIAL DOSE** | | | | |
| J0476 | Injection, baclofen, 50 mcg for intrathecal trial | Updated quarterly, most current information can be downloaded from CMS website[3] | | |
| **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 $262 | $36 | $123 |
| 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 $262 | $48 | $130 |
| 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 $298 | $95 | $95 |
| 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 $245 | $41 | $122 |

**GABLOFEN® (BACLOFEN INJECTION)**

| 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] |

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**

| 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 |


†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: March 28, 2018.

2 https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/Hospitaloutpatientpps/Downloads/2018-April-Addendum-B.zip. Last accessed: March 28, 2018.

3 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html. Last accessed: March 28, 2018.

Full Prescribing Information attached. For more information, visit www.gablofen.com or call the Reimbursement Hotline: 833-570-2159.

# Gablofen® (baclofen injection)

## INDICATIONS AND USAGE

- 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.

## 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.**

## 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.

**To report suspected adverse reactions, call 888.525.8114, contact the FDA at 800.FDA.1088 or www.fda.gov/medwatch.**

**Full Prescribing Information attached. For more information, visit www.gablofen.com or call the Reimbursement Hotline: 833-570-2159.**

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