

Coding and Billing Information

SMOFlipid[®] injectable emulsion, USP 20%

The information and guidance within this document are intended for educational purposes related to SMOFlipid[®] only and is not a complete listing of all coding requirements for all insurance plans. Coverage and Coding requirements vary by insurance companies and by plans offered by insurance companies. These policies are constantly evolving by payers without notice and should be verified by the provider for each patient prior to treatment. Information provided by this document is not a guarantee of coverage or payment of SMOFlipid[®]. It is the sole responsibility of the provider to select proper codes and ensure the accuracy of all claims used in seeking reimbursement.

Brand Name: SMOFlipid[®]

Generic Name: lipid injectable emulsion, USP 20%

SMOFlipid[®] Indication Selected Safety Information¹:

WARNING: DEATH IN PRETERM INFANTS

See full prescribing information for complete boxed warning

- Deaths in preterm infants have been reported in literature. **(5.1, 8.4)**
- Autopsy findings included intravascular fat accumulation in the lungs. **(5.1, 8.4)**
- Preterm and low birth weight infants have poor clearance of intravenous lipid emulsion and increased free fatty acid plasma levels following lipid emulsion infusion. **(5.1, 8.4)**

SMOFlipid[®] is indicated in adults as a source of calories and essential fatty acids for parenteral nutrition when oral or enteral nutrition is not possible, insufficient or contraindicated.

Limitations of Use:

The Omega-6: Omega-3 fatty acid ratio and Medium Chain Triglycerides in SMOFlipid[®] have not been shown to improve clinical outcomes compared to other intravenous lipid emulsions.

Description:

SMOFlipid[®] is a sterile, nonpyrogenic, white, homogenous lipid emulsion for intravenous infusion. The lipid content of SMOFlipid[®] is 0.20 g/mL, and comprises a mixture of soybean oil, medium-chain triglycerides (MCTs), olive oil, and fish oil.

¹ SMOFlipid[®] Prescribing Information

Coding

Including:

- **NDC** (National Drug Code, assigned by the FDA to identify specific drugs)
- **ICD-10-CM** (International Classification of Diseases, 10th Revision, Clinical Modification, assigned by WHO, World Health Organization to classify diagnoses, used in all places of service)
- **HCPCS** (Healthcare Common Procedure Coding System assigned by CMS to identify products or procedures)

The NDC Codes below are assigned to “SMOFlipid[®]” (also known as: sterile lipid injectable emulsion with a lipid content of 0.2 gram/mL), a human prescription drug labeled by “Fresenius Kabi USA, LLC”.

NDC	Description	Concentration	Fill Volume
63323-820-00	Lipid Injectable Emulsion, USP 20%	20 grams per 100mL (0.2 grams per mL)	100 mL
63323-820-74	Lipid Injectable Emulsion, USP 20%	50 grams per 250mL (0.2 grams per mL)	250 mL
63323-820-50	Lipid Injectable Emulsion, USP 20%	100 grams per 500 mL (0.2 grams per mL)	500 mL
63323-820-10	Lipid Injectable Emulsion, USP 20%	200 grams per 1000 mL (0.2 grams per mL)	1000 mL

For reimbursement purposes, some payers may require the Healthcare Provider to include NDCs on the claim form. For claims-reporting purposes, some payers may also require HCPs to convert the 10-digit NDC to an 11-digit NDC by adding a “0” (zero) where appropriate to create a 5-4-2 configuration. The zero is added in front of the second segment of numbers when the 10-digit format is the 5-3-2 configuration. Below is an example of converting a 10-digit NDC to an 11-digit NDC for SMOFlipid[®]: NDC 63323-820-00 would become NDC 63323-0820-00

NDC - National Drug Code (The NDC, or National Drug Code, is a unique 10-digit or 11-digit, 3 segment number, and a universal product identifier for human drugs in the United States.

The 3 segments of the NDC identify:

- The labeler (Segment #1)
- The product (Segment #2)
- The commercial package sizes (Segment #3)

ICD-10-CM - International Classification of Diseases, 10th Revision, Clinical Modification
Daily parenteral nutrition is considered reasonable and necessary for a patient with severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient’s general condition.

Below is a table of common diagnosis codes that may be covered by an insurance company. Patient specific diagnosis should be validated with the patient’s insurance company. This list is not all inclusive, but only a small list of possibilities:

Description	Diagnosis Code
Malabsorption due to intolerance, not elsewhere classified	K90.48
Complete intestinal obstruction, unspecified as to cause	K56.601
Acute Infarction of intestine, part and extent unspecified	K55.069
Postsurgical malabsorption, not elsewhere classified	K91.2
Acquired absence of other specified parts of digestive tract	Z90.49
Fistula of Stomach and duodenum	K31.6
Gastroenteritis and colitis due to radiation	K52.0
Gastrointestinal transplantation	Z94.82
Irritable Bowel Syndrome	K58.1

Payer Types

Medicare - a federal system of health insurance for people over 65 years of age and for certain younger people with disabilities. Medicare coverage is categorized into four groups:

Part A - Hospital Inpatient

Part B - Durable Medical Equipment, prosthetics/orthotics and Enteral/Parenteral Nutrition

Part C - Medicare Advantage plans

Part D - Prescription Drug Coverage

SMOFlipid® is considered a parenteral nutrition lipid emulsion and therefore covered by Part B, Medicare. Medicare coverage is administered by commercial insurance companies that contract with Medicare. Commercial insurers that have been awarded the Part B contracts are called DME-MACs (Durable Medical Equipment Medicare Administrative Contractors).

Below is a table that provides the names of the commercial insurers that have been awarded the DME-MAC contracts for 2020 by state:

2020 Medicare Administrative Carrier Contracts for DME-MAC Coverage

Jurisdiction	States Covered	Medicare Administrative Carrier (MAC)
Jurisdiction A	CT DE DC MD ME ML NH NJ NY PA RI VT	Noridian Healthcare Solutions
Jurisdiction B	IL ID KY MI MN OH WI	CGS, A Celerian Group Company
Jurisdiction C	AL AK CO FL GA LA MS NM NC OK PR SC TN TX U.S. VIRGIN ISLANDS VA WV	CGS, A Celerian Group Company
Jurisdiction D	AK AMERICAN SAMOA AZ CA GUAM HW ID IA KS MO MT NB NV ND NORTHERN MARIANA ISLANDS OR SD UT WA WY	Noridian Healthcare Solutions

Medicare Advantage - Medicare beneficiaries are offered Medicare coverage via commercial insurance companies that at a minimum Medicare coverage, but often enhanced benefits. These plans are also referred to as Part C.

Medicaid - A federal/state system of health insurance for those patients requiring financial assistance.

Commercial - Health insurance that is typically offered via an employer or purchased by the patient directly from a for-profit insurance company.

Coverage Policy

Medicare

The following is a brief summary of Medicare's coverage of parenteral nutrition. Medicare's coverage policy is particularly important due to the fact that other insurance types (Medicare Advantage, Medicaid and Commercial) often follow Medicare's coverage policy.

Medicare's coverage of Parenteral Nutrition is standardized by implementation of a National Coverage Determination (NCD) for Enteral and Parenteral Nutritional Therapy (180.2). This means that all Medicare patients across the U.S. have the same benefits and are held by the same coverage criteria.

Parenteral Nutrition Coverage Criteria:

Parenteral Nutrition Therapy is considered reasonable and necessary for a patient with severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition. Coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision, which requires that the patient must have a permanently inoperative internal body organ or function thereof. Therefore, parenteral nutritional therapy is normally not covered in situations involving temporary impairments.

Parenteral nutrition therapy claims must be as a result of a physician's written order or prescription to prove medical necessity. DME MACs will only reimburse for 30-day supplies at a time.

To qualify for coverage of Parenteral Nutrition, the following requirements must be met:

- To qualify for Medicare coverage of Parenteral Nutrition the patient is required to have severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition. PN must be administered 7 days per week and PN is required for a minimum of 90 days.
- A total caloric daily intake (parenteral, enteral, and oral) of 20-35 cal/kg/day is considered sufficient to achieve or maintain appropriate body weight. The ordering physician must document in the medical record the medical necessity for a caloric intake outside this range in an individual patient.

- The ordering physician must document the medical necessity for protein orders outside of the range of 0.8-1.5 gm/kg/day, dextrose concentration less than 10%, or lipid use greater than 1500 grams (150 units of service of code B4185) per month.
- Prescription/Orders - Medicare requires a DME Information Form (DIF) be completed, signed, and dated by the supplier, must be kept on file by the supplier and made available upon request. The DIF for parenteral nutrition is CMS Form 10126. The initial claim must include an electronic copy of the DIF. CMS 10126 - ENTERAL AND PARENTERAL NUTRITION
- Medical Records - Physician prescription documenting continued need/use if applicable. The patient's diagnosis must be severe pathology of the alimentary tract, which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition.
- Correct Coding - HCPCS codes correct to the product administered, ICD-10 diagnosis codes to document qualifying diagnosis
- Proof of Delivery - Signed delivery slip or proof of delivery via shipping

Prior Authorization

Medicare requires precertification/prior authorization for Parenteral Nutrition. A precertification number should be placed in Box 23 of the DMS 1500 claim form.

Most insurance plans require a Prior Authorization be submitted prior to provision of SMOFlipid® to a patient. Please contact the patient's insurance company to identify required forms and how/where to submit the Prior Authorization.

Product Coding

HCPCS codes (Healthcare Common Procedure Coding System) identify a specific product. Below is a table that demonstrates what codes have been suggested by payers. Provision of these codes is not a guarantee that the codes will be accepted by every payer. Check with each patient's insurance company for coverage of these codes.

SMOFlipid® Lipid Injectable Emulsion, USP 20%

NDC	Fill Volume	Description	Concentration	HCPCS Code Options - Lipids
63323-820-00	100 mL	Lipid Injectable Emulsion, USP 20%	20 grams per 100 mL (0.2 grams per mL)	*B4185 - Parenteral Nutrition Solution, Not Otherwise Specified, 10 Grams Lipids
63323-820-74	250 mL	Lipid Injectable Emulsion, USP 20%	50 grams per 250 mL (0.2 grams per mL)	*B4185 - Parenteral Nutrition Solution, Not Otherwise Specified, 10 Grams Lipids

NDC	Fill Volume	Description	Concentration	HCPCS Code Options - Lipids
63323-820-50	500 mL	Lipid Injectable Emulsion, USP 20%	100 grams per 500 mL (0.2 grams per mL)	*B4185 - Parenteral Nutrition Solution, Not Otherwise Specified, 10 Grams Lipids
63323-820-10	1000 mL	Lipid Injectable Emulsion, USP 20%	200 grams per 1000 mL (0.2 grams per mL)	*B4185 - Parenteral Nutrition Solution, Not Otherwise Specified, 10 Grams Lipids

*HCPCS Code B4185 should be billed with a billing unit of "1" for each 10 Grams. When administered for a 30-day period at 40g per day, the total billing units would be 120.

If an **IV Pole and infusion pump** are also used, the coding used could be:

Equipment	HCPCS Code
IV Pole	E0776
Parenteral Nutrition Infusion Pump, Stationary	B9006
Parenteral Nutrition Supply Kit; Premix, Per Day	B4220
Parenteral Nutrition Administration Kit, Per Day	B4224

If the coverage requirements for parenteral nutrition are met, one supply kit (B4220) and one administration kit (B4224) will be covered for each day that parenteral nutrition is administered. For example, June has 30 days in it, therefore the billing unit when billing for the month of June should be "30". This number should be in box 24G on the CMS 1500 claim form.

Modifiers:

A Modifier that apply to the IV Pole or ambulatory infusion pump is "RR" - Rental. Append to appropriate code when billing rental items (inexpensive, capped rental, items that require servicing. Modifiers are to be placed in Box 24D of the CMS-1500. Up to 4 modifiers can be attached to each HCPCS code.

Place of Service Codes

Place of Service Codes tell the insurance company where SMOFlipid® is administered. The Place of Service code should be placed in Box 24B of the CMS-1500. Coverage of Parenteral Nutrition is based on the patient's place of service. Products are either paid for using HCPCS codes and payment amounts on the payer's fee schedule or on a "Per Diem" rate. Per Diem means the facility is paid a daily or monthly amount to provide all services to the patient, which includes their daily nutritional needs. Per Diem rates apply to hospital inpatient or Skilled Nursing Facilities.

Place of Service Code	Place of Service Name	Place of Service Description	Coverage of Parenteral Nutrition
12	Home	Location, other than hospital or other facility, where the patient receives care in a private residence	Billed with HCPCS codes
13	Assisted Living Facility	Congregate residential facility with self-contained living units providing assessment of each resident's needs and on-site support 24 hrs. per day, 7 days a week	Billed with HCPCS codes
21	Inpatient Hospital	A facility, that primarily provides diagnostic, therapeutic and rehab services by supervision of physicians admitted due to medical condition	Considered a "Per Diem" situation. Hospitals are paid a fixed rate that includes parenteral nutrition
24	Ambulatory Surgical Center	A freestanding facility other than a physician's office, where surgical and diagnostic services are provided on an ambulatory basis	Billed with HCPCS codes
31	Skilled Nursing Facility	A facility that provides inpatient skilled nursing to patients but does not provide level of care available in a hospital	Considered a "Per Diem" situation. Skilled facilities are paid a fixed rate that includes parenteral nutrition

Performing a Benefit Verification

Coverage criteria for each individual patient should be validated by contacting the patient's insurance company directly. This process is called a "Benefit Verification". The phone number for the Benefits or Customer Service department at the patient's insurance company should be on the back side of the patient's insurance card.

Some of the information to be gathered from the insurance company during a Benefit Verification can include:

Benefit Verification Questions to Patient Insurance:

- Is Prior Authorization Required?
- What is the insurer's Prior Authorization process?
- What is the fax or telephone number to the Prior Authorization unit within the insurer?
- What information will the Prior Authorization unit request?
- How long does the Prior Authorization process take?
- What is the patient's out of pocket cost?
 - Co-payment/Co-insurance
 - Deductible
- Has the patient met their annual or lifetime benefit max?

- What amount has been paid to date?
 - Annual Deductible
 - Lifetime Benefit
 - Out of pocket maximum
- What is the telephone number to your Claims Inquiry department?
- What is the address to submit claims to?
- Do you have any documentation requirements? (e.g. Statement of Medical Necessity)

To report suspected adverse reactions, contact Fresenius Kabi USA, LLC, at 1-800-551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Disclaimer:

Information that has been provided is not a guarantee of coverage of SMOFlipid®. Benefits, billing and coding requirements should always be verified with the specific patient's insurance plan. Benefits and Coverage is typically unique to a patient's insurance plan, not just the insurance company in general. Level of coverage varies by plan type within an insurance company. Coverage information provided within this document is subject to change without notice and is only as accurate as the information provided by the payers. It is the sole responsibility of the provider to select proper codes and ensure the accuracy of all claims used in seeking reimbursement.

Please see accompanying Full Prescribing Information, including Boxed Warning or go to freseniuskabinutrition.com

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