FRESENIUS KABI

caring for life

SMOFlipid®

lipid injectable emulsion, USP 20%

Billing & Coding Guide for Healthcare Professionals

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Product Information

Brand Name: SMOFlipid®

Generic Name: lipid injectable emulsion, USP 20%

SMOFlipid® Indications and Usage:

SMOFlipid® is indicated in adult and pediatric patients, including term and preterm neonates, as a source of calories and essential fatty acids for parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.

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.

IMPORTANT SAFETY INFORMATION

For intravenous infusion only into a central or peripheral vein. Use a non-vented non-DEHP 1.2 micron in-line filter set during administration. Recommended dosage depends on age, energy expenditure, clinical status, body weight, tolerance, ability to metabolize and eliminate lipids, and consideration of additional energy given to the patient. The recommended dose for adults and pediatrics is shown in Table 1. For information on age-appropriate infusion rate, see the full prescribing information. SMOFlipid Pharmacy Bulk Package is only indicated for use in pharmacy admixture programs for the preparation of three-in-one or total nutrition admixtures. Protect the admixed PN solution from light.

Table 1: Recommended Adult and Pediatric Dosage

Age	Nutritional Requirements	
	Initial Recommended Dosage	**Maximum Dosage**
Birth to 2 years of age (including preterm and term neonates)	0.5 to 1 g/kg/day	3 g/kg/day
Pediatric patients 2 to <12 years of age	1 to 2 g/kg/day	3 g/kg/day
Pediatric patients 12 to 17 years of age	1 g/kg/day	2.5 g/kg/day
Adults	1 to 2 g/kg/day	2.5 g/kg/day

SMOFlipid is contraindicated in patients with known hypersensitivity to fish, egg, soybean, peanut, or any of the active or inactive ingredients, and severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglycerides >1,000 mg/dL).

Clinical Decompensation with Rapid Infusion of Intravenous Lipid Emulsion in Neonates and Infants: Acute respiratory distress, metabolic acidosis, and death after rapid infusion of intravenous lipid emulsions have been reported.

Parenteral Nutrition-Associated Liver Disease: Increased risk in patients who received parenteral nutrition for greater than 2 weeks, especially preterm neonates. Monitor liver tests; if abnormalities occur consider discontinuation or dosage reduction.

Hypersensitivity Reactions: Monitor for signs or symptoms. Discontinue infusion if reactions occur.

Risk of Infections, Fat Overload Syndrome, Refeeding Syndrome, Hypertriglyceridemia, and Essential Fatty Acid Deficiency: Monitor for signs and symptoms; monitor laboratory parameters.

Aluminum Toxicity: Increased risk in patients with renal impairment, including preterm neonates.

Most common adverse drug reactions (≥5%) from clinical trials in adults were nausea, vomiting, and hyperglycemia. Most common adverse drug reactions (≥5%) from clinical trials in pediatric patients were anemia, vomiting, increased gamma-glutamyltransferase, and nosocomial infection.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176, option 5, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

This Important Safety Information does not include all the information needed to use SMOFlipid safely and effectively. Please see full prescribing information, for intravenous use at www.FreseniusKabiNutrition.com.

Prescribing Information:
To access **SMOFlipid®** Prescribing Information, please use the QR code or link below.

https://freseniuskabinutrition.com/SMOFlipidPI

[1]SMOFlipid Prescribing Information, Fresenius Kabi USA LLC. 2023

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)

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)

The NDC Codes below are assigned to SMOFlipid® (also known as: 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 (HCP) 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 63323-820-20 would become NDC 63323-0820-00

ICD-10-CM – International Classification of Diseases, 10th Revision, Clinical Modification

Parenteral nutrition is the provision of nutritional requirements intravenously and the various insurance plans (Medicare, Medicaid, Commercial, etc.) may have specific policies pertaining to parenteral nutrition medical necessity requirements for patients.

Coding (continued)

Below is a table of applicable common diagnosis codes that may be covered by an insurance company. Patient specific diagnosis should be validated with the patient's insurance company. The list below provides examples of possible diagnosis codes and is not all inclusive:

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

HCPCS Coding (Healthcare Common Procedure Coding System)

HCPCS codes (Healthcare Common Procedure Coding System) identify a specific product. Below is a table that lists the HCPCS code options for SMOFlipid®. Provision of these codes is not a guarantee that the codes will be accepted by every payer. It is important to verify coverage of these codes with each patient's insurance plan.

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
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

Billing Units: 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.

Coding (continued)

Coding for Equipment and Supplies

The following HCPCS codes are associated with the listed equipment and supplies:

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, 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.

When parenteral nutrition is administered in an outpatient facility, the pump used for its administration and IV pole will be denied as not separately payable. The pump and pole are not considered as rentals to a single beneficiary, but rather, as items of equipment used for multiple beneficiaries. Services associated with the administration of parenteral nutrition in a beneficiary's home are not a covered benefit administered by the DME MACs.

Modifiers:
When an IV pole (E0776) is used in conjunction with parenteral nutrition, the BA modifier should be added to the code. Code E0776 is the only code with which the BA modifier may be used. Modifiers are to be placed in Box 24D of the CMS-1500. Up to 4 modifiers can be attached to each HCPCS code.

Coding (continued)

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, which primarily provides diagnostic, therapeutic, and rehab services by, or under supervision of physicians to patients admitted due to various medical conditions	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

Payer Types

Medicare – A federal system of health insurance for people who are 65 years of age or older, for certain younger people with disabilities, and for people with end-stage renal disease (ESRD). Medicare coverage is categorized into four groups:

Part A – Hospital Inpatient
Part B – Durable Medical Equipment (prosthetics/orthotics and Enteral/Parenteral Nutrition), Outpatient, Home Health
Part C – Medicare Advantage Plans
Part D – Prescription Drug Coverage

SMOFlipid® is considered a parenteral nutrition product. Parenteral nutrition that is eligible for coverage under Medicare Part B is billed to the respective DME-MAC (Durable Medical Equipment Medicare Administrative Contractor).

Below is a table that provides the names of the commercial insurers that have been awarded the DME-MAC contracts for 2022 by state:

2022 Medicare Administrative Contractors for DME-MAC Coverage

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

Medicare Advantage – Medicare coverage via commercial insurance companies that offer an alternative to Traditional Medicare by providing bundled coverage for Part A, Part B, and usually Part D. 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 was previously standardized by implementation of a National Coverage Determination (NCD) for Enteral and Parenteral Nutritional Therapy (180.2.) However, effective 01/01/2022 Medicare's coverage for Parenteral Nutrition was standardized by a Medicare Local Coverage Determination (LCD) L38953 that can be accessed at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38953

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

Medicare Advantage and Commercial Insurance

For Medicare Advantage, according to federal law, Part C providers must provide their beneficiaries with all services and supplies that Traditional Medicare Parts A and B cover (Medicare.org). However, coverage policies for Medicare Advantage insurance plans should be verified.
For Commercial insurance plans, coverage policies will vary and should be verified.

Parenteral Nutrition Coverage

Medicare

As per Medicare LCD L38953, "For parenteral nutrition to be considered reasonable and necessary, the treating practitioner must document that enteral nutrition has been considered and ruled out, tried and been found ineffective, or that EN exacerbates gastrointestinal tract dysfunction. The beneficiary must have (a) a condition involving the small intestine and/or its exocrine glands which significantly impairs the absorption of nutrients or (b) disease of the stomach and/or intestine which is a motility disorder and impairs the ability of nutrients to be transported through and absorbed by the gastrointestinal (GI) system. The beneficiary must have a permanent impairment." However, as per LCD-related Policy Article (A58836), "this does not require a determination that there is no possibility that the beneficiary's condition may improve sometime in the future. If the medical record, including the judgement of the treating practitioner, indicates that the impairment will be of long and indefinite duration, the test of permanence is considered met." The LCD-related Policy Article (A58836) can be accessed at: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58836.

Below is a listing of several of the Medicare coverage requirements for Parental Nutrition. Please refer to LCD L38953 and the LCD-related Policy Article (A58836) for a more complete listing of coverage requirements.

- Test of Permanence – Coverage of parenteral nutrition requires that a beneficiary must have a permanent impairment. However, this does not require a determination that there is no possibility that the beneficiary's condition may improve sometime in the future. If the medical record, including the judgment of the treating practitioner, indicates that the impairment will be of long and indefinite duration, the test of permanence is considered met.

- The treating practitioner is required to evaluate the beneficiary within 30 days prior to initiation of parenteral nutrition. If the treating practitioner does not see the beneficiary within this timeframe, they must document the reason why and describe what other monitoring methods were used to evaluate the beneficiary's parenteral nutrition needs. There must be documentation in the medical record supporting the clinical diagnosis.

- Nutrients – A total caloric daily intake of 20-35 cal/kg/day is considered reasonable and necessary to achieve or maintain appropriate body weight. The treating practitioner must document the medical necessity for a caloric intake outside this range in an individual beneficiary.

- The treating practitioner must document the medical necessity for protein orders outside of the range of 0.8-2.0 gm/kg/day (B4168, B4172, B4176, B4178), dextrose concentration less than 10% (B4164, B4180), or lipid use per month in excess of the product-specific, FDA-approved dosing recommendations (B4185, B4187).

- Special nutrient formulas, HCPCS codes B5000, B5100, and B5200 are produced to meet the unique nutrient needs for specific disease conditions. The beneficiary's medical record must adequately document the specific condition and the necessity for the special nutrient.

Parenteral Nutrition Coverage (continued)

- Prescription/Orders – A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. 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 form for parenteral nutrition is CMS 10126 –ENTERAL AND PARENTERAL NUTRITION. The initial claim must include an electronic copy of the DIF. No more than one month's supply of parenteral nutrients, equipment or supplies is allowed for one month's prospective billing.

- Medical Records – Documentation in the medical record shall reflect that the beneficiary has (a) a condition involving the small intestine and/or its exocrine glands which significantly impairs the absorption of nutrients or (b) disease of the stomach and/or intestine which is a motility disorder and impairs the ability of nutrients to be transported through and absorbed by the gastrointestinal (GI) system. Suppliers are required to monitor the beneficiary's medical condition to confirm that the coverage criteria for parenteral nutrition continue to be met.

- Correct Coding – An item/service must meet all coding guidelines established by CMS.

- Proof of Delivery – Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files.

Medicare Advantage and Commercial Insurance

Compared to Traditional Medicare, Medicare Advantage plans may have additional rules related to network status, member cost share, and authorization requirements. Commercial insurance plans may have different coverage and authorization criteria for Parenteral Nutrition. For Medicare Advantage and Commercial insurance plans, coverage criteria requirements should be verified.

Benefit Verification and Authorization

Performing a Benefit Verification

Coverage criteria for each individual patient should be validated by contacting the patient's insurance company directly.

Below is some important information to be gathered from the insurance company during a Benefit Verification:

Questions to Ask During Insurance Verification:

- Confirm eligibility – Is the patient's plan current?
- What is the provider's network status?
- Are the reimbursement codes valid and billable?
- What is the patient's out of pocket cost?
  - Co-payment/Co-insurance
  - Deductible Amount and Accumulation
  - Maximum Out-of-Pocket and Accumulation
- Has the patient met their lifetime benefit max?
- What is the address to submit claims to?

Prior Authorization

Medicare does not require precertification/prior authorization for Parenteral Nutrition. However, it is important that medical documentation include the requirements outlined within the Medicare Parenteral Nutrition LCD L38953 and the related Article A58836.

Some insurance plans, including Medicare Advantage and Commercial, may require a Prior Authorization for SMOFlipid®.

Questions to Ask Regarding Prior Authorization:

- 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, including any supporting documentation?
- How long does the Prior Authorization process take?

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Fresenius Kabi is a global healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion, and clinical nutrition. Our products are used to help care for critically ill and chronically ill patients in hospitals, long-term care facilities, and at home. For more information about Fresenius Kabi, please visit **www.fresenius-kabi.com/us**.

For information on **SMOFlipid**® (lipid injectable emulsion, USP 20%), visit **https://freseniuskabinutrition.com/products/smoflipid-adults/** or **https://freseniuskabinutrition.com/products/smoflipid-pediatrics/**.

For Fresenius Kabi product availability and ordering call **1-888-386-1300**.

For Medical Information call 1-800-551-7176 (option 4) or email **nutrition.medinfo.USA@fresenius-kabi.com**.

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047
Phone: 1.888.386.1300
www.fresenius-kabi.com/us