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RETIRED

Effective Date: 10/08/2020

Omegaven® (fish oil triglycerides)

FDA approval: July 27, 2018

HPCS: B4185

Benefit: Medical

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. Patient must be 15 years old or younger
 - b. Used as a source of calories for pediatric patients diagnosed with parenteral nutrition-associated cholestasis (PNAC)
 - c. PNAC diagnosis must be made prior to receiving Omegaven as Omegaven is indicated for PNAC treatment and not prevention
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limit: FDA approved dosing
 - b. Initial Authorization Period: 1 year
 - c. Renewal Criteria: Clinical improvement of PNAC. Continue until direct or conjugated bilirubin levels are < 2 mg/dL or until the patient no longer requires parenteral nutrition.
 - d. Renewal Authorization Period: 1 year
- C. Omegaven is considered investigational when used for all other conditions, including but not limited to:
 - a. Adult parenteral nutrition associated liver injury
 - b. Prevention of PNAC
 - c. Rheumatoid arthritis

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

Therapeutic considerations:

A. FDA approved indication / Diagnosis

- a. Used as a source of calories for pediatric patients diagnosed with parenteral nutrition-associated cholestasis (PNAC)
- b. Limitation of Use: Omegaven has not been FDA approved for the prevention of PNAC, only treatment

**Please refer to most recent prescribing information.*

[Omegaven Prescribing Information](#)

B. Background Information

- a. Omegaven is the first fish-oil based lipid emulsion approved in the US. It has been available through compassionate use protocols
- b. 40-60% of pediatric long term parenteral nutrition (PN) patients will develop parenteral nutrition associated cholestasis (PNAC)
- c. PNAC is thought to be caused by many factors, primarily bowel resection in premature infants, followed by immature liver function, inflammatory mediators, short bowel syndrome (SBS), infections, and lack of internal feeding
- d. Prior to Omegaven, FDA approved PN formulations such as Intralipid were soybean lipid emulsions rich in omega-6 fatty acids, which is suspected to cause liver injury because excessive omega-6 fatty acids have proinflammatory effects and impair triglyceride export
- e. Soy-based lipid emulsions also contain phytosterols that reduce bile secretion and may contribute to liver injury
- f. By contrast, fish oil-based emulsions are rich in omega-3 fatty acids (including EPA and DHA), which tend to have anti-inflammatory and insulin-sensitizing effects, likely mediated by the GPR120 receptor
- g. Not only does evidence suggest that fish oil formulations do not contribute to the incidence of PNAC, but patients receiving Omegaven after developing it have a higher rate of reversal when compared to patients who received soy- based emulsion

C. Efficacy

**Please refer to most recent prescribing information.*

D. Medication Safety Considerations

Boxed Warning: No

**Please refer to most recent prescribing information.*

E. Dosing and administration

- a. Dosing: The recommended daily dose (and maximum dose) in pediatric patients is 1 g/kg/day for infusion into a central or peripheral vein

**Please refer to most recent prescribing information.*

F. How supplied

- a. Single-dose injectable emulsion: 5 g/50 mL, 10 g/100 mL

References:

1. Omegaven [prescribing information]. Graz, Austria: Fresenius Kabi; 2018.
2. Intestinal failure-associated liver disease in infants. Kathleen M Gura, PharmD, BCNSP, FASHP, Scott A Elisofon, MD. UpToDate.
3. Parenteral Nutrition-Induced Cholestasis in Neonates: Where Does the Problem Lie? Jolin-Dahel K, Ferretti E, Monitveros C et al; Gastroenterology Research and Practice; vol 2013 article ID 163632. October 2013.
4. Park HW, Lee NM, Kim JH, et al. Parenteral Fish Oil–Containing Lipid Emulsions May Reverse Parenteral Nutrition–Associated Cholestasis in Neonates: A Systematic Review and Meta-Analysis. The Journal of Nutrition. 2015; 145: 277- 83. doi:10.3945/jn.114.204974.
5. Intralipid [prescribing information]. Uppsala, Sweden: Fresenius Kabi; 2015.
6. SMOFlipid [prescribing information]. Uppsala, Sweden: Fresenius Kabi; 2016.
7. Fliesler N. A Life-Saving Adjustment in IV Nutrition Cleared by the FDA. Boston Children's Hospital. Available at: <https://vector.childrenshospital.org/2018/08/omegaven-clears-fda/>. Accessed September 10, 2018.
8. Intravenous Fish Oil Helping Premies and Babies Who Can't Eat. University Health System. Available at: <https://www.universityhealthsystem.com/news/2013/05/intravenous-fish-oil-helping-babies>. Accessed September 10, 2018.
9. Raman M, Almutairdi A, Mulesa L, et al. Review: Parenteral Nutrition and Lipids. Journal of Nutrients. 2017; 9: 388. doi:10.3390/nu9040388 www.mdpi.com/journal/nutrients.

Policy History												
#	Date	Change Description										
1.2	Effective Date: 10/08/2020	Retiring policy as this drug is no longer managed with prior authorization										
1.1	Effective Date: 11/07/2019	Annual Review of Medical Policy										
1.0	Effective Date: 11/01/2018	New Policy<table><tr><th>Line of Business</th><th>PA Required (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
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* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.