ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Urgent**[1] ☐ **Non-Urgent**

Requested Drug Name: Omontys® (peginesatide)

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit: ☐ New Request ☐ Reauthorization

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Omontys® (peginesatide)

Diagnosis (documentation supportive of diagnosis is required for approval)

☐ Treatment of anemia due to CKD
☐ Patient on dialysis
☐ Other (please state): _____

Clinical Consideration

☐ Hemoglobin level that is <10g/dL within the last 4 weeks

Physician Specialty (diagnosis made by):

☐ Nephrologist
☐ Other (please state): _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):			
Drug Name (Brand Name and Scientific Name)/Strength:			
Dose:	Route:	Frequency:	
Quantity:	Number of Refills:		
Product will be delivered to: ☐ Patient's Home ☐Physician Office		Other:	
Prescriber or Authorized Signature:		Date:	
Dispensing Pharmacy Name and Phone Number:			
☐ **Approved** ☐ **Denied**			
If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:			

1. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request

RMHP Formulary Coverage Policy

Omontys® (peginesatide)

CLASSIFICATION

- Erythropoiesis-stimulating agent (ESA)

DESCRIPTION

- A synthetic, pegylated peptide that binds to and activates the human erythropoietin receptor and stimulates erythropoiesis. Its structure differs from the other erythropoiesis-stimulating agents (ESAs) in that it does not have an amino acid sequence homology to Epo.
- Omontys is indicated for the treatment of **anemia** due to chronic kidney disease (**CKD)** in adult patients **on dialysis.**
- Omontys is NOT indicated for:
  - use in patients with CKD who are not on dialysis
  - patients with anemia due to treatment for cancer because ESAs have demonstrated harm in some settings and the benefit-risk factors for Omontys in this setting have not been assessed.
  - as a substitute for RBC transfusions in patients who require immediate correction of anemia
- Omontys has not been shown to improve symptoms, physical functioning or health-related QOL.
- **Black Box Warning:** Erythropoiesis-stimulating agents (ESAs) increase the risks for death, myocardial infarction, stroke, and other serious cardiovascular events. In clinical studies, patients with chronic kidney disease (CKD) had a greater risk for death, serious adverse cardiovascular reactions, and stroke when administered ESAs to target Hb levels of 11 g/dL or higher. No trial has identified a Hb target level, ESA dose, or dosing strategy that does not increase these risks. Therefore, in patients with CKD, use the lowest sufficient dose to reduce the need for RBC transfusion.
- EMERALD-1 [n = 793] and EMERALD-2 [n = 815] evaluated patients with CKD on dialysis who had previously been treated with epoetin alfa or epoetin beta. These randomized, active-controlled, open-label, multicenter trials (n=1608) found both peginesatide once monthly noninferior to epoetin 1 to 3 times weekly. Both maintained Hb levels in the prespecified range of 10 to 12 g/dL for 29 to 36; the proportion of patients with serious CV events was not significantly different with peginesatide compared with epoetin.
- Adverse Events (occurring in ≥ 10% of patients) in the two EMERALD studies where diarrhea, nausea, vomiting, dyspnea, cough, arteriovenous fistula site complication, procedural hypotension, headache, muscle spasms, extremity pain, back pain, arthralgia, hypotension, hypertension, pyrexia, hyperkalemia, and upper respiratory tract infection. These were similar to the adverse effects in the epoetin-treated patients.
- Pure Red Cell Aplasia (PRCA), a rare but serious adverse reaction, did not occur in patients given Omontys during clinical trials.
- A prospective cardiovascular composite safety end point (CSE) of death, myocardial infarction, stroke and serious adverse events of congestive heart failure, arrhythmia and unstable angina demonstrated similar risk for Omontys compared with epoetin alfa/beta in patients with anemia in CKD patients on dialysis. HOWEVER, in CKD patients not on dialysis, CSE events occurred more frequently with Omontys than with Aranesp (22% vs. 17%).

FORMULARY COVERAGE

Prior authorization: Required
Good Health Formulary: Tier 6
Commercial Formulary: Tier 6
Medicare Part D coverage: ESRD; Tier 3 with clinical and b/d prior authorization

COVERAGE CRITERIA

Omontys® (peginesatide) meets the definition of **medical necessity** for the following:

- Treatment of anemia in patients with chronic kidney disease who are on dialysis.
  - Documentation supportive of diagnosis is required and should include lab work and clinical notes.
  - A hemoglobin level of <10g/dL needs to be provided from lab work that occurred within the last 4 weeks.
- Coverage authorization period is granted in 1 year intervals.

Omontys® (peginesatide) is considered **experimental** for the following:

- Any condition or diagnosis not FDA approved or Compendia supported, including use in patients with CKD who are not on dialysis; use in patients with anemia due to treatment for cancer because ESAs have demonstrated harm in some settings and the benefit-risk factors for Omontys in this setting have not been assessed; or as a substitute for RBC transfusions in patients who require immediate correction of anemia.

Required Provider Specialty:

- Approval is limited to Nephrologists

DOSAGE/ADMINISTRATION

Adult Dosing (safety and efficacy has not been determined for pediatric patients less than 18 years):

- For anemia due to CKD in adult patients on dialysis:
  - Initiate therapy when hemoglobin (Hb) is < 10.0 g/dL.
  - The recommended starting dose is 0.04 mg/kg given as a single IV or SC injection once monthly in those who are not currently receiving ESA therapy.
  - Conversion from another ESA: Dose once monthly based on the total weekly epoetin or darbepoetin alfa dose at the time of conversion. Maintain the route of administration (IV or SC injection).
  - Estimated starting doses when switching patients previously established on epoetin or darbepoetin to Omontys is detailed in the Omontys prescribing information.
  - SC can be administered patient after training from a health care provider
  - If peritoneal dialysis - must administer Omontys by SC route only

PRECAUTIONS

- **Black Box Warning:** Erythropoiesis-stimulating agents (ESAs) increase the risks for death, myocardial infarction, stroke, and other serious cardiovascular events. In clinical studies, patients with chronic kidney disease (CKD) had a greater risk for death, serious adverse cardiovascular reactions, and stroke when administered ESAs to target Hb levels of 11 g/dL or higher. No trial has identified a Hb target level, ESA dose, or dosing strategy that does not increase these risks. Therefore, in patients with CKD, use the lowest sufficient dose to reduce the need for RBC transfusion.
- **Contraindications:** Uncontrolled hypertension
- **Precautions:**
  - CKD with Hb > 11 g/dL due to increased risk of death, myocardial infarction, stroke, congestive heart failure, thrombosis of hemodialysis vascular access, or other thromboembolic events; use the lowest dose needed to avoid RBC transfusions.
  - CKD with insufficient Hb response to therapy; may be at a greater risk for cardiovascular reactions and mortality than other patients; dosage adjustment or discontinuation may be needed.
  - CKD not on dialysis; may increase risk for death, myocardial infarction, stroke, congestive heart failure, unstable angina, or arrhythmia; use not recommended

- In controlled trials, ESAs increase the risk of death in patients undergoing CABG surgery and increased the risk of DVT in patients undergoing orthopedic procedures.
- Use in cancer patients is not recommended. It may shorten survival and/or increase risk of tumor progression or recurrence.
- Patients with coexistent cardiac disease may have an increased risk of serious cardiovascular events and death.
- Failure to respond or maintain a response possibly due to iron deficiency, infection, inflammation, or bleeding may require dosage adjustment or discontinuation.
- If typical causes for lack or loss of response are excluded, anti-erythropoietin antibody-associated anemia should be suspected. For assays for binding and neutralizing antibodies contact Affymax, Inc (1-855-466-6689)
- Patients on Omontys may require adjustment in dialysis prescription and increased anticoagulation with heparin to prevent clotting of the extracorporeal circuit during hemodialysis.
- A hemoglobin increase in excess of 1 g/dL within a 2-week period may increase risk for death, myocardial infarction, stroke, congestive heart failure, thrombosis of hemodialysis vascular access, and other thromboembolic events. Dosage adjustment may be needed.
- Patients with coexistent stroke have increased risk of serious cardiovascular events and death.

Billing/Coding information

CPT Coding:

90935	Hemodialysis procedure with single physician evaluation
90937	Hemodialysis procedure requiring repeated evaluation(s) with or without substantial revision of dialysis prescription
90940	Hemodialysis access flow study to determine blood flow in grafts and arteriovenous fistulae by an indicator method
90960 90961 90962	End-stage renal disease related services monthly, for patients 20 years of age and older; with 4 or more face-to-face physician visits per month -With 2 to 3 face-to-face physician visits per month -With 1 face-to-face physician visit per month
90969	End-stage renal disease related services for dialysis less than a full month of service, per day for patients 12-19 years of age
90970	End-stage renal disease related services for dialysis less than a full month of service, per day for patients 20 years of age and older
90999	Unlisted dialysis procedure, inpatient or outpatient
96372 96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular -Intravenous push, single or initial substance/drug

HCPCS Coding:

Q2047	Injection, peginesatide, 0.1mg (for ESRD on dialysis)

COST

- AWP (July 2012): Omontys IV/SC 0.04 mg/kg for a 70kg person (2.8mg/month): $363.16
  - $12.97 per 0.1mg

COMMITTEE APPROVAL

- July 2012

GUIDELINE UPDATE INFORMATION

July 2012	Prior authorization ad Coverage policy created

REFERENCES

- DRUGDEX®, accessed 07/17/2012.
- Product Information: Omontys® (peginesatide), injection for intravenous or subcutaneous use. Takeda Pharmaceutical America, Inc., Deerfield, IL, 2012.