

State of California—Health and Human Services Agency Department of Health Care Services



March 16, 2020

RE: Blood Factor Utilization Management – COVID-19 Sixty Day Supply Exception

Dear Contracted Medi-Cal Specialty Provider:

The Department of Health Care Services (DHCS) continues to closely monitor the emerging 2019 Novel Coronavirus (COVID-19) situation. This letter is to inform you that, until June 1, 2020, unless reauthorized by a subsequent letter, DHCS will permit an exception related to Section IV (F) of the Medi-Cal Supplemental Provider Contract for Specialty Services, Performance Obligations, and allow a sixty (60) day supply of clotting factor for those patients where an interruption to product supply may be imminent. Providers must notify DHCS in writing if they will be taking advantage of this exception. Without such notice, providers may be considered in violation of Article 3.7 of the Agreement. Written notification may be emailed to: specialtyproviders@dhcs.ca.gov.

If a product normally requires prior authorization (TAR/SAR), providers are advised to incorporate the statement "Patient impacted by COVID-19" within the Miscellaneous Information field on the TAR/SAR. Providers may also consider a one-time early refill to accommodate a two week cushion for patient on prophylaxis therapy.

Additionally, although Section V (F) of the Contract is <u>not</u> being amended, providers should consider the expiration date in these situations and, if possible, provide product with a four (4) month or greater expiration date.

Providers are reminded the Medi-Cal Supplemental Provider Contract, Section VI (G), requires providers to have operating procedures in place to support a Disaster Plan which should include an extended home supply if applicable.

Medi-Cal Supplemental Provider Contract for Specialty Services, Performance Obligations, Sections:

IV (F): Provider shall proactively contact beneficiaries on a regular schedule to monitor home inventory levels (as per severity) and ensure an adequate supply of blood factor is available, preventing overstocking of greater than 30 days of inhome inventory and maintaining reportable records to support therapy

compliance. Records must be maintained for audit purposes and available upon request.

V (F): Blood factor concentrates shall have acceptable outdates based on diagnosis and frequency of treatment. Beneficiaries using a prophylactic regimen shall have a product outdate of 3 months or later. Beneficiaries using an ondemand regimen shall have a product outdate of 6 months or later. Beneficiaries using an infrequent demand therapy (less than 6 times a year) shall have a product outdate of one year or more. Expiration dates shall be excused during times of manufacturer-documented shortages. Expired product in beneficiary possession must be reported to the DHCS quarterly. Report shall include the total units expired and the date dispensed to the beneficiary.

VI (G): Provider must maintain internal documented operational procedures to support a disaster plan in the event of a disaster interrupting stock and delivery mechanisms. The provider must maintain current training materials, and an internal tracking mechanism to measure performance against the policy. Providers shall have a plan in place to meet delivery requirements in the event of a natural disaster or other emergency.

Please note, Hemlibra is <u>not</u> a clotting factor and therefore not subject to the performance obligations associated with the Medi-Cal Supplemental Provider Contract for Specialty Services. Current Medi-Cal policy allows the use of a greater than thirty (30) day supply of most drugs, including Hemlibra. When requesting prior authorization (TAR/SAR) approval of a 60 day supply of Hemlibra, providers are advised to incorporate the statement "Patient impacted by COVID-19" within the Miscellaneous Information field on the TAR/SAR.

If you have questions about this notice, please contact DHCS by email at Specialtyprovider@dhcs.ca.gov.