| Field Name | Field Description |
|---|---|
| Prior Authorization Group Description | **Primary Hemophagocytic Lymphohistiocytosis (HLH) Agents** |
| Drugs | Gamifant (emapalumab-lzsg) |
| Covered Uses | Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines. |
| Exclusion Criteria | Members who have undergone hematopoietic stem cell transplantation (HSCT) |
| Required Medical Information | "See Other Criteria" |
| Age Restrictions | N/A |
| Prescriber Restrictions | Hematologist, Oncologist, Immunologist, Transplant Specialist, or other specialist experienced in the treatment of immunologic disorders |
| Coverage Duration | Initial Authorization: 1 month<br>Reauthorization: 3 months |
| Other Criteria | ***Gamifant will only be approved for members who have not yet received HSCT and will be discontinued at the initiation of HSCT***<br><br>****Drug is being requested through the member's medical benefit****<br><br>**Initial Authorization**<br>• Member has a diagnosis of Primary HLH<br>• ~~Member does NOT have a diagnosis of Secondary HLH due to a proven rheumatic or neoplastic disease or an infection~~<br>• Prescriber attests that member has not achieved a satisfactory response to or is intolerant to conventional HLH therapy (e.g. etoposide, dexamethasone) or has recurrent disease<br>• Prescriber attests that the member is a candidate for hematopoietic stem cell transplant (HSCT)<br>• Member has been screened for latent tuberculosis infection<br>• Member has or will receive prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, *Pneumocystis jirovecii*, and other fungal infections<br>• Dosing is consistent with FDA approved labeling<br><br>**Reauthorization**<br>• Member continues to meet initial authorization criteria |

| | |
|---|---|
| Revision/Review Date ~~6/2021~~ **4/2023** | • Member is receiving prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, *Pneumocystis jirovecii*, and other fungal infections<br>• ~~HSCT has not yet been initiated for member~~<br><br>**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.** |