Blue Cross Blue Shield Blue Care Network of Michigan

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P&T Date: 04/10/2025

Denosumab Products

Desonusmab-dssb
Jubbonti® (denosumab-bbdz)
Osenvelt (denosumab-bmwo)
Ospomyv™ (denosumab-dssb)
Prolia® (denosumab)
Stoboclo (denosumab-bmwo)
Wyost® (denosumab-bbdz)
Xgeva® (denosumab)
Xbryk™ (denosumab-dssb)

HCPCS: Desonusmab-dssb: J3590; Jubbonti: Q5136; Osenvelt: J3590; Ospomyv: J3590; Prolia: J0897; Stoboclo: J3590; Wyost: Q5136; Xgeva: J0897; Xbryk: J3590

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. For the prevention of skeletal-related events in patients with multiple myeloma or with bone metastases from solid tumors (Xgeva or Xgeva biosimilar only) when the criteria below are met:
      i. Documentation that at least one IV bisphosphonate has been ineffective, not tolerated or contraindicated
      OR
      ii. National Comprehensive Cancer Network (NCCN) supported category 1 preferred agent for prevention of skeletal related events in patients with bone metastases for the specific oncological diagnosis
   b. For the treatment of adults and skeletally mature adolescents with giant cell tumor of bone (Xgeva or Xgeva biosimilar only) when all of the criteria below are met:
      i. Documentation of confirmed giant cell tumor of bone and radiologic evidence of measurable disease (via CT scan or MRI)
      ii. Bone is unresectable or surgical resection is likely to result in severe morbidity
   c. For the treatment of hypercalcemia of malignancy (HCM) refractory to bisphosphonate therapy (Xgeva or Xgeva biosimilar only) when all of the criteria below are met:
      i. Diagnosis of hypercalcemia secondary to a malignancy (including hematologic malignancies)
      ii. Albumin corrected serum calcium (CSC) ≥ 12mg/dL (3.0mmol/L)
      iii. Documentation that at least one IV bisphosphonate has been ineffective, not tolerated or contraindicated

d. For the treatment of osteoporosis (Prolia or Prolia biosimilar only) when all of the criteria below are met:
    i. FDA approved diagnosis
    ii. At least one bisphosphonate (if patient has intolerance to oral administration, IV administration will be required) is not effective (such as reduction of T-score or fracture) except if:
        a) Treatment with bisphosphonates (oral and intravenous formulations) are not tolerated or contraindicated
e. To increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer OR women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for nonmetastatic breast cancer (Prolia or Prolia biosimilar only) when all of the criteria below are met :
    i. When the 10-year probability of hip fracture is ≥ 3% or the 10-year probability of a major osteoporosis-related fracture is ≥ 20%
    ii. At least one bisphosphonate (if patient has intolerance to oral administration, IV administration will be required) is not effective (such as reduction of T-score or fracture) except if:
        a) Treatment with bisphosphonates (oral and intravenous formulations) are not tolerated or contraindicated
f. Will NOT be used in combination with any anabolic bone modifying agent or bisphosphonate
g. Coverage will be provided for biosimilar products for FDA labeled indications of the innovator product when criteria are met.
h. Trial and failure of the preferred products as specified in the BCBSM/BCN medical utilization management drug list

B. Quantity Limitations, Authorization Period and Renewal Criteria
    a. Quantity Limits: Align with FDA recommended dosing
    b. Authorization Period: 6 months for initial approval and one year at a time for renewal
    c. Renewal Criteria:
        i. Xgeva or Xgeva biosimilar (multiple myeloma or bone metastases from solid tumors and breast cancer): If more than 1 fracture in the last 6 months alternative therapy is recommended
        ii. Xgeva or Xgeva biosimilar (giant cell tumor of the bone): Goals of therapy have been met
        iii. Xgeva or Xgeva biosimilar (hypercalcemia of malignancy): Decrease in albumin CSC levels from baseline
        iv. Prolia or Prolia biosimilar: Documentation of improved or stable T-scores while on Prolia

***Note: Coverage and approval duration 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

Background Information:

- Denosumab is a fully human monoclonal antibody against the receptor activator of nuclear factor-kB ligand (RANKL). RANKL is a cytokine that is essential for the formation, function, and survival of osteoclasts. By binding RANKL, denosumab prevents the interaction of RANKL with its receptor on osteoclasts and osteoclast precursors and reversibly inhibits osteoclast-mediated bone resorption. As a monoclonal antibody, denosumab has potential safety risks/significant safety concerns that must be balanced against its potential benefits. Due to its mechanism of action, denosumab presents a novel approach to fracture prevention.

- Bisphosphonates are currently the most predominantly prescribed treatments and have a proven history of safety and efficacy.

- Osteoporosis:

    - Approximately 54 million people in the United States have osteoporosis or another form of low bone mass. Breakdown of bone structure may be the result of natural aging and calcium deficiency (e.g., senile osteoporosis) or due to hormonal changes as in post-menopause. The decrease in bone mass and deterioration of bone tissue in osteoporosis can result in bone fragility and potential for fractures. Fractures related to osteoporosis and bone loss are a concern because of the high morbidity and mortality rate and economic burden. The National Osteoporosis Foundation estimates that 1 in 2 women and 1 in 4 men over 50 years of age will break a bone as a result of osteoporosis, resulting in $19 billion in related costs every 2 years and 2 million broken bones.

    - There are numerous randomized controlled trials (RCTs) assessing the efficacy of denosumab. However, only one trial studied the clinically meaningful endpoint of fracture prevention. All other efficacy trials used percent change in bone mineral density (BMD) as the primary endpoint. BMD is a surrogate marker and change in BMD is poorly correlated to fracture prevention. There is one placebo-controlled trial that established the efficacy of denosumab (Prolia) with regard to decreased fracture risk. Denosumab (Prolia) reduces the risk of vertebral, hip, and non-vertebral fractures in post-menopausal women with osteoporosis over 36 months when compared to placebo.

    - Denosumab (Prolia) has not been proven in reliable clinical studies to be more effective than bisphosphonates for treatment of osteoporosis.

    - There are trials comparing denosumab (Prolia) to oral alendronate and IV zoledronic acid for the treatment of osteoporosis in post-menopausal women. The primary endpoint of these trials is BMD changes at 12 and 24 months which is not as clinically relevant as fracture data. One small RCT demonstrated greater osteoporotic fracture reduction for denosumab compared to alendronate; however, future longitudinal studies with longer follow-up and larger sample sizes are needed to confirm the efficacy difference between denosumab and bisphosphonates.

    - The FRAX® tool (www.shef.ac.uk/FRAX) was developed by the World Health Organization (WHO) to evaluate fracture risk of patients. It integrates clinical risk factors with BMD at the femoral neck. The FRAX® tool provides the 10-year probability of fracture. The output is a 10-year probability of hip fracture and a 10-year probability of major osteoporotic fracture (forearm, shoulder, or clinical vertebral fracture).

    - Treatment should be considered if the 10-year risk is 3% or more for hip fracture or 20% or more for “major” osteoporosis-related fracture based on the US-adapted WHO algorithm (FRAX® tool).

    - The American Association for Clinical Endocrinology (AACE)/American College of Endocrinology (ACE) guidelines (2020) define osteoporosis as a BMD T-score at or lower than -2.5. However, a non- or low-traumatic fracture (fragility fracture) is considered osteoporosis regardless of T-score. The AACE guidelines include the following recommendations:

        - AACE/ACE guidelines separate patients with osteoporosis into two categories – high risk or very high risk. Patients who have had a recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than − 3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX® (e.g., major osteoporosis fracture > 30%, hip fracture > 4.5%) or other validated fracture risk algorithm should be considered to be at very high fracture risk. All other patients who have been diagnosed with osteoporosis but are not at very high fracture risk, as defined above, are considered to be high risk.

- The Endocrine Society 2020 Guidelines for the Pharmacological Management of Osteoporosis in Postmenopausal Women separate patients into 4 categories. Their high risk and very high risk categories align with those defined by the AACE/ACE guidelines. However, they also identify patients as low risk if they have no prior hip or spine fractures, a BMD T-score at the hip and spine both above −1.0, a 10-year hip fracture risk < 3%, and 10-year risk of major osteoporotic fractures < 20% or moderate risk when they have no prior hip or spine fractures, a BMD T-score at the hip and spine both above −2.5, and 10-year hip fracture risk < 3% or risk of major osteoporotic fractures < 20%.

- The AACE recommends either bisphosphonates (IV or oral) or denosumab as initial treatment options for patients with high risk osteoporosis without prior fracture. Guidelines do not give preference to one antiresorptive therapy over another. Bisphosphonates decrease the breakdown of bone and have been shown to increase BMD and reduce the incidence of fractures in patients with osteoporosis. Contraindications to bisphosphonates include hypocalcemia and severe renal impairment. In addition, oral bisphosphonates are contraindicated in patients with the inability to stand or sit upright for at least 30 minutes and may not be an appropriate option in patients with underlying gastrointestinal issues. However, use of IV bisphosphonates is still appropriate in these situations.

- There is evidence to support the superiority of certain antiresorptive agents (Prolia and IV zoledronate) and anabolic agents (Evenity®, Tymlos®, and Forteo®) over oral bisphosphonates for individuals who are unable to use oral bisphosphonates and as initial therapy for individuals with osteoporosis who are considered to be at very high risk for fracture, such as those with a T-score less than -3.0 or those with a history of fracture. These guidelines do not give preference to one therapy over another.

- The Endocrine Society guidelines recommend initial treatment of patients at moderate risk with bisphosphonates (oral or IV) as initial therapy. For patients in the high to very high risk categories, the treatment algorithm recommends bisphosphonates, denosumab, teriparatide, abaloparatide, or romosuzumab all with adjunct calcium and vitamin D therapy as their treatment options.

- Sequential treatment with a bisphosphonate or denosumab (Prolia) is recommended after discontinuation of an anabolic agent to prevent bone density decline and loss of fracture efficacy.

- Until the effect of combination therapy on fracture risk is better understood, the AACE does not recommend concomitant use of FDA approved osteoporosis agents for the prevention or treatment of postmenopausal osteoporosis.

- The goal of monitoring osteoporosis therapy is to identify those who have significant bone loss. AACE recommends a repeat DXA scan 1 to 2 years after initiation of therapy until bone density is stable. Bone turnover markers (BTMs) are also useful for assessing patient compliance and efficacy of therapy. Reductions in BTMs are conferred by antiresorptive therapy and are associated with fracture reduction. Significant increases in BTMs indicate good response to anabolic therapy.

- A drug holiday is not recommended for denosumab (Prolia), and treatment with denosumab should be continued for as long as clinically appropriate. If denosumab therapy is discontinued, patients should be transitioned to another antiresorptive therapy.

- Glucocorticoid-Induced Osteoporosis:

    - A 24-month international, multi-center, double-blind, active-controlled, double-dummy, non-inferiority study compared denosumab to risedronate. Of the 795 patients enrolled, 505 were glucocorticoid-continuing and 290 were initiating therapy. Denosumab was both non-inferior and superior to risedronate at 12 months for effect on BMD at the lumbar spine in both glucocorticoid-continuing (4.4% [95% CI 3.8–5.0] vs 2.3% [1.7–2.9]; p<0.0001) and glucocorticoid-initiating (3.8% [3.1–4.5] vs 0.8% [0.2–1.5]; p<0.0001) subpopulations. Incidence of adverse events, serious adverse events (including infections), and fractures was similar between treatment groups.

    - Guidelines from the American College of Rheumatology (ACR) for the prevention and treatment of glucocorticoid-induced osteoporosis (GIOP; 2022) include the following recommendations:

        - A strong recommendation for usage of oral bisphosphonates over no treatment for adults ≥ 40 years old receiving long-term glucocorticoids who are at high or very high risk for fracture.

        - Other agents including IV bisphosphonates, parathyroid hormone/parathyroid hormone related protein (PTH/PTHrP: Foteo or Tymlos), and denosumab are also options that are conditionally recommended. However, ACR notes that the evidence for fracture reduction for denosumab and PTHrP has been demonstrated in general osteoporosis but not GIOP. In addition, ACR states that the denosumab trials were not powered to detect reductions of GIOP fractures and instead use a surrogate endpoint of BMD changes and that the relationship between increases in BMD and a decrease in vertebral fractures is inconsistent.

- Prevention of Osteoporosis Due to Hormone Suppression:

    - In breast and prostate cancer patients on hormone suppression therapy, hormone suppression increases bone turnover and decreases bone mineral density (BMD). Oral bisphosphonates are the best value for the prevention of osteoporosis in patients on hormone suppression therapy.

    - There is a limited body of evidence for fracture prevention during hormone suppression therapy. Clinical trials were designed to demonstrate an increase in BMD without evidence of fracture prevention. BMD is a surrogate for fracture risk, the more clinically meaningful measure of efficacy.

    - For prevention of osteoporosis in patients with prostate cancer during androgen deprivation therapy (ADT): there is evidence that denosumab, pamidronate, zoledronic acid, and alendronate increase BMD during ADT. NCCN Prostate Cancer guidelines version 3.2024 (March 8, 2024) recommend (category 2a) denosumab every 6 months, zoledronic acid once annually, or alendronate 70 mg once weekly when risk of fracture warrants treatment. Zoledronic acid increases BMD when administered every three months OR annually. There is no comparative evidence that demonstrates that more frequent dosing is more effective. One randomized, double-blind prospective study that compared denosumab compared to oral alendronate in 234 male patients undergoing ADT for prostate cancer found that denosumab was associated with a lower rate of new vertebral fractures; however, additional randomized clinical studies are warranted to establish the superiority of denosumab in this clinical setting.

    - There is evidence to support the use of antiresorptive agents (bisphosphonates and denosumab) to maintain or improve bone mineral density and reduce the risk of fractures in postmenopausal women who are receiving adjuvant aromatase inhibitor therapy. Unlike bisphosphonates, which have demonstrated an overall survival (OS) benefit when used as adjuvant therapy, there is no available data showing an OS benefit with denosumab. Therefore, the NCCN Breast Cancer guidelines version 2.2024 (March 11, 2024) recommend bisphosphonate therapy for postmenopausal patients receiving adjuvant endocrine therapy.

- Giant Cell Tumor of Bone (GCTB):

    - Several Phase II trials have examined the efficacy of denosumab for treating primary and recurrent giant cell tumor of the bone (GCTB). In an open-label, Phase II study (N = 37), denosumab induced tumor response (defined as elimination of at least 90% of giant cells or no radiologic progression of the target lesion for up to 25 weeks) in 86% of patients with unresectable or recurrent GCTB.

    - The NCCN Bone Cancer guidelines version 2.2024 (March 12, 2024) recommend denosumab and/or serial embolization as preferred options for patients with lesions that are resectable with unacceptable morbidity and/or unresectable axial lesions. Following primary treatment, patients with stable or improved disease can be observed. Intralesional excision is recommended if the lesion becomes resectable. Patients with unresectable disease should be re-treated with denosumab, serial embolization, and/or radiation therapy (non-preferred). Guidelines recommend continuation of treatment until disease progression.

- Cancer-Related Bone Metastases:

    - Zoledronic acid (Zometa®) provides the best value for prevention of skeletal complications, decreasing the incidence and rate of skeletal events, and delaying skeletal events in women with breast cancer with bone metastases. The effectiveness of denosumab was evaluated in 7,201 patients with various advanced cancers including metastatic breast, prostate, and various other solid tumor cancers. There are four RCTs comparing denosumab (Xgeva) with zoledronic acid (Zometa) for the prevention of skeletal-related events (SRE) related to bone metastases.

        - SRE related to bone metastases were defined as pathological fractures, spinal cord compression, and bone complications that required radiation or surgery.

        - The pooled result demonstrated that denosumab (Xgeva) was significantly superior to zoledronic acid (Zometa) in delaying the time to the first skeletal related event (HR: 0.86; 95% CI: 0.80-0.93; $p < 0.01$), and time to first-and-subsequent SREs (RR: 0.87; 95% CI: 0.81-0.93, $p < 0.01$). However, no significant differences were observed between the two groups in regard to overall survival (OS) or time to disease progression. Additionally, denosumab (Xgeva) was associated with higher incidence of hypocalcemia and osteonecrosis of the jaw (ONJ) compared to zoledronic acid (Zometa). Further analysis is warranted for the comparison of denosumab (Xgeva) and zoledronic acid (Zometa) for advanced cancer with bone metastasis.

    - Denosumab (Xgeva) extends the time to first SRE by six months in patients with metastatic breast cancer. As a secondary endpoint the number of SREs was reported (number of SREs is the more commonly reported endpoint in efficacy trials). In the metastatic breast cancer trial, 30.7% of denosumab (Xgeva) subjects had an SRE compared with 36.5% of zoledronic acid (Zometa) subjects. This small difference of 5.8%, coupled with the dropout rate of 18% could have influenced the magnitude of difference between the products. It is unclear that that the treatment effect would be as robust if the subjects who left the trial early had completed the trial.

    - The claim of superiority in other metastatic solid tumor cancers including prostate cancer is uncertain due to the small treatment effect and high drop-out rates. The drop-out rate (patients who did not complete the trial for reasons other than having an on-study SRE, death or disease progression) was greater than 22% in both trials. Therefore, it is uncertain that study groups remained adequately randomized and balanced by the end of the trials for a fair comparison.

- Prevention of SRE in Patients with Multiple Myeloma (MM):

    - A randomized, double blind, active controlled, noninferiority trial compared denosumab and zoledronic acid. It enrolled 1,718 patients with newly diagnosed MM. The study met its primary endpoint. Denosumab was found to be non-inferior to zoledronic acid in delaying the time to first SRE following randomization, with a median time of 22.8 months for denosumab and 24 months for zoledronic acid (HR = 0.98, 95% CI, 0.85-1.14). An SRE was defined as a pathologic fracture, radiation therapy to bone, surgery to bone, or spinal cord compression. The results for overall survival (OS) were comparable between Xgeva and zoledronic acid treatment groups with a hazard ratio of 0.90 (95% CI: 0.70, 1.16).

    - The NCCN Guidelines for Multiple Myeloma version 3.2024 (March 8, 2024) recommend bisphosphonates (category 1) or denosumab (category 2a) for all patients receiving therapy for symptomatic MM regardless of documented bone disease. With respect to duration of therapy, the guidelines recommend continuing bone-targeting treatment for up to 2 years and continuing beyond 2 years based on clinical judgement.

- Clinical Efficacy in Hypercalcemia of Malignancy (HCM):

    - HCM is a serious complication that is indicative of poor malignancy prognosis. It results from cancer-driven increases in bone resorption, and if untreated, can lead to renal failure, progressive mental impairment, coma, and death.

    - The classification of severity of hypercalcemia is as follows:

        - Mild hypercalcemia: albumin-corrected serum calcium (CSC) <12 mg/dL

        - Moderate hypercalcemia: albumin CSC between 12 and 14 mg/dL

        - Severe hypercalcemia: albumin CSC >14 mg/dL

- Denosumab (Xgeva) acts by inhibiting the osteoclast-mediated bone resorption, which results in decrease in bone destruction and calcium release thus lowering calcium levels in HCM patients.

- An open-label, single-arm study evaluated 33 patients with advanced cancer and persistent hypercalcemia (CSC of 12.5mg/dL or higher) after recent bisphosphonate treatment. The primary endpoint was the proportion of patients with a response (defined as albumin CSC <11.5 mg/dL within 10 days after the first dose of Xgeva).

- The secondary endpoints included the proportion of patients who experienced a complete response (defined as CSC <10.8 mg/dL by day 10), time to response, and response duration (defined as the number of days from the first occurrence of CSC <11.5 mg/dL).

- Please refer to study results in Table 1 below:

Table 1: Efficacy of Xgeva in Patient with HCM Refractory to Bisphosphonate Therapy

Endpoint	N = 33	Proportion (%)
All Responders (CSC≤ 11.5 mg/dL) by day 10	21	63.6
All Responders by Day 57	23	69.7
Complete Responders (CSC≤ 10.8 mg/dL) by day 10	12	36.4
All Complete Responders by Day 57	21	63.6

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Policy History		
#	Date	Change Description
3.2	Effective Date: 04/10/2025	Added Xbryk, Ospomyv, Stoboclo, and Osenvelt, removed specific timeline for trial of bisphosphonates, and defined what would be considered a failure (such as reduction of T-score or fracture)
3.1	Effective Date: 03/20/2025	UM medical management system update for BCBS and BCN for Osenvelt
3.0	Effective Date: 03/13/2025	UM medical management system update for BCBS and BCN for Denosumab and Stoboclo
2.9	Effective Date: 02/28/2025	UM medical management system update for BCBS and BCN for Xbryk and Ospomyv
2.8	Effective Date: 11/03/2024	UM medical management system update for MAPPO and BCNA for Jubbonti
2.7	Effective Date: 04/11/2024	Updated to include Jubbonti and Wyost
2.6	Effective Date: 03/21/2024	UM medical management system update for BCBS and BCN for Wyost and Jubbonti
2.5	Effective Date: 04/06/2023	Updated policy to clarify duration of initial authorization period for Prolia and Xgeva
2.4	Effective Date: 10/06/2022	Shortened duration of bisphosphonate trial to 12 months for osteoporosis indication for Prolia; removed requirement for calcium/vitamin D supplementation for all indications; will not allow for combination therapy with bisphosphonates in addition to anabolic therapies
2.3	Effective Date: 10/07/2021	Annual Review of Medical Policy
2.2	Effective Date: 10/08/2020	Annual Review
2.1	Effective Date: 11/7/2019	Policy update for: trial and failure of oral and IV bisphosphonates, trial and failure of preferred products, combination therapy for osteoporosis diagnosis
2.0	Effective Date: 08/15/2019	Policy update for Xgeva indications of multiple myeloma and solid tumors based on NCCN guidelines
1.9	Effective Date: 08/09/2018	Policy update added new Xgeva indication: multiple myeloma and new Prolia indication: glucocorticoid-induced osteoporosis
1.8	Effective Date: 05/03/2018	Annual Review of Medical Policy

1.7	Effective Date: 07/05/2017	UM medical management system update for MAPPO and BCNA for Prolia and Xgeva
1.6	Effective Date: 05/04/2017	Changes: Annual Review/Medicare Disclaimer added
1.5	Effective Date: 11/10/2016	Annual review; No changes to criteria, document template updated.
1.4	Effective Date: 05/07/2015	Policy update added new indication: hypercalcemia of malignancy (HCM)
1.3	Effective Date: 08/14/2014	Criteria update to treatment of osteoporosis and including continuation of therapy
1.2	Effective Date: 05/02/2013	Criteria update
1.1	Effective Date: 01/22/2013	UM medical management system update for Prolia and Xgeva
1.0	Effective Date: 11/08/2012	New Policy. UM medical management system update for BCN for Prolia and Xgeva

** 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.*

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Medication Authorization Request Form

Blue Cross Blue Shield Blue Care Network of Michigan

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This form is to be used by participating physicians to obtain coverage for **drugs covered under the medical benefit**. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	**Name**
ID Number	**Specialty**
D.O.B. ☐Male ☐Female	**Address**
Diagnosis	**City /State/Zip**
Drug Name	**Phone/Fax: P**: ( ) - **F**: ( ) -
Dose and Quantity	**NPI**
Directions	**Contact Person**
Date of Service(s)	**Contact Person Phone / Ext.**

STEP 1: DISEASE STATE INFORMATION

1. Is this request for: ☐ Initiation ☐ Continuation *Date patient started therapy:* _____
2. Administered by patient or a medical professional? ☐ patient (self) ☐ health care professional (physician, nurse, etc.)
3. Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
   ☐ Hospital outpatient facility (go to #4) *Reason for Hospital Outpatient administration:* _____
   ☐ Hospital inpatient facility for Car-T therapy only (for example: Kymriah, Yescarta, or Tecartus) (go to #5)
4. Please specify location of administration if hospital outpatient infusion: _____
5. Please specify location of administration if hospital inpatient infusion: _____
6. Please provide the NPI number for the place of administration: _____
7. **Initiation AND Continuation of therapy:**
   a. What is the patient's diagnosis? _____
   b. What other medication has the patient received for their condition? Please list_____
      i. Please describe the response to previous therapies:
      _____
   c. Will the patient be receiving any other treatment for the listed condition while on this medication? Please list:
      _____
   d. Please list any labs values important for diagnosing or monitoring this patient's condition:
      _____
8. **Continuation of therapy:**
   a. Has the patient progressed while on this medication? ☐ yes ☐ no
   b. How has the patient's condition changed while on this medication?
      ☐ Improved: Please describe: _____
      ☐ Stable: please describe: _____
      ☐ Worsened; Please describe: _____
      ☐ Other; Please describe: _____

Chart notes are required for the processing of all requests. Please add any other supporting medical information necessary for our review **(required)**

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name **Physician Signature** **Date**

Step 2: Checklist	☐ Form Completely Filled Out ☐ Provide chart notes	☐ Attach test results
Step 3: Submit	**By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979**	**By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320**

7/26/2018, 9/18/2018; 1/31/2020; 3/17/2020; 8/9/2021