Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Denied	**Appeal Number:**	2203049
Decision Date:	5/25/2022	**Hearing Date:**	05/04/2022
Hearing Officer:	Patricia Mullen		

Appearance for Appellant:

[redacted]

Appearances for Accountable Care Organization (ACO):
Felicia Hughes, Manager of Member Appeals & Grievances; Atty. Shannon Choy-Seymour, Associate General Counsel; Dr. Jessica Rubinstein, Senior Medical Director; Dr. Jessica Amorosino, Medical Director

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
Board of Hearings
100 Hancock Street, Quincy, Massachusetts 02171

APPEAL DECISION

Appeal Decision:	Denied	**Issue:**	Prior authorization/ Pharmacy
Decision Date:	5/25/2022	**Hearing Date:**	05/04/2022
ACO's Reps.:	Felicia Hughes, Manager of Member Appeals & Grievances; Atty. Shannon Choy-Seymour, Associate General Counsel; Dr. Jessica Rubinstein, Senior Medical Director; Dr. Jessica Amorosino, Medical Director	**Appellant's Rep.:**	[redacted]
Hearing Location:	Quincy Harbor South		

Authority

This hearing was conducted pursuant to Massachusetts General Laws Chapter 118E, Chapter 30A, and the rules and regulations promulgated thereunder.

Jurisdiction

Through a notice dated March 25, 2022, Boston Medical Center HealthNet, Well Sense Health Plan (hereinafter "BMC HealthNet"), a MassHealth accountable care organization (ACO), informed the appellant that it had denied her internal appeal of a denial of a prior authorization (PA) request for the prescription medication Gammagard liquid, 10% vial, because BMC HealthNet determined that the request did not meet BMC HealthNet pharmacy policy nor MassHealth guidelines for medical necessity. (130 CMR 450.204; Exhibit 1). The appellant filed this appeal with the Board of Hearings (BOH) in a timely manner on April 20, 2022. (130 CMR 610.032(B) and Exhibit 2). An ACO's denial of a request for prior authorization is valid grounds for appeal to BOH (130 CMR

610.032(B)(2)).[1]

Action Taken by ACO

BMC HealthNet denied the appellant's request for prior authorization for the prescription medication Gammagard liquid 10% vial.

Issue

The appeal issue is whether MassHealth's agent or designee, BMC HealthNet, was correct, pursuant to 130 CMR 450.204; 406.413(C), to deny the appellant's internal appeal of a denial of a prior authorization request for the prescription medication Gammagard liquid 10% vial.

Summary of Evidence

The appellant was represented telephonically by her neurologist, who she authorized to represent her at the hearing. (Exhibit 2). BMC HealthNet was represented telephonically by its Manager of Member Appeals & Grievances (hereinafter "BMC's representative"), its Associate General Counsel, its Senior Medical Director, and its Medical Director. The appellant is between the ages of 21 and 65 and is enrolled in BMC HealthNet's Well Sense ACO. (Testimony).

BMC's representative testified that the appellant's neurologist submitted a request for prior authorization for the prescription medication Gammagard liquid 10% vial (hereinafter "Gammagard") to Express Scripts, BMC HealthNet's pharmacy benefit manager, on March 22, 2022, for treatment of the appellant's small fiber neuropathy. (Exhibit 9, p. 9). Gammagard is an intravenous immune globulin (IVIG). (Exhibit 1, testimony). On March 23, 2022, Express Scripts denied the request for coverage of Gammagard because the appellant's diagnosis is not listed as a covered diagnosis under BMC HealthNet's clinical criteria for coverage of Gammagard. (Exhibit 9, p. 9). On March 23, 2022, the appellant's neurologist submitted an appeal to BMC HealthNet. (Exhibit 9, p. 9). The appellant's neurologist wrote that Gammagard is requested for the appellant's diagnosis of small fiber neuropathy and fibromyalgia. (Exhibit 9, p. 28). The appellant's neurologist wrote that given that the appellant has multiple autoimmune diseases and presence of multiple autoantibodies in her blood, and her symptoms developed after a serious infection and prolonged antibiotic therapy, he had a strong suspicion that the appellant's small fiber neuropathy may respond to IVIG therapy. (Exhibit 9, p. 28).

On March 24, 2022, BMC HealthNet sent the case to an external peer review neurologist for review and recommendation. (Exhibit 9, p. 9, testimony). The peer review neurologist noted that the

[1] An accountable care organization is defined at 130 CMR 501.001 as an entity that enters into a population-based payment model contract with EOHHS as an accountable care organization, wherein the entity is held financially accountable for the cost and quality of care for an attributed or enrolled member population. ACOs include Accountable Care Partnership Plans, Primary Care ACOs, and MCO-Administered ACOs.

appellant has small fiber neuropathy confirmed by skin biopsy and intradermal nerve fiber density testing. (Exhibit 9, p. 23). Based on a review of BMC HealthNet Well Sense Plan Pharmacy Policy for Immune Globulin, policy number 9.110, the peer review neurologist recommended denial of coverage of the Gammagard because the medication has not been determined medically necessary for the treatment of small fiber neuropathy. (Exhibit 9, p. 23). On March 25, 2022, a BMC HealthNet physician reviewer, in consultation with the external, peer review neurologist, denied the appeal of the denial of coverage for Gammagard because the appellant's diagnoses are not covered as medically necessary under the BMC HealthNet's Pharmacy Policy for Gammagard. (Exhibit 9, pp. 49-61). By notice dated March 25, 2022, BMC HealthNet informed the appellant that the request for Gammagard was denied because the appellant does not have a diagnosis approved for use of IVIG therapy and there is little significant clinical evidence of how well IVIG works in treating the appellant's condition. (Exhibits 1, 9, p. 11).

The BMC HealthNet Pharmacy Policy (hereinafter "the Policy") sets forth the criteria necessary for coverage of IVIG medications, including Gammagard, at Policy Number 9.110. (Exhibit 9, pp. 49-73). The Policy notes that coverage of IVIG is recommended in patients who meet one of the following criteria, and thereafter lists the covered Federal Drug Administration (FDA) approved indications, as well as other approved diagnoses and conditions. (Exhibit 9, pp. 49-61). The Policy lists 28 approved indications, diagnoses, and conditions, and neither small fiber neuropathy nor fibromyalgia appear on the list, and in fact fibromyalgia is listed as excluded. (Exhibit 9, pp. 49-60). The Policy notes that coverage is excluded when IVIG is prescribed for conditions in which there is insufficient clinical evidence to support its use. (Exhibit 9, p. 60).

BMC's Senior Medical Director testified that BMC HealthNet and MassHealth have similar criteria for coverage of Gammagard and BMC HealthNet's criteria is not more restrictive than MassHealth's criteria. BMC's Senior Medical Director noted that the three papers cited by the appellant's neurologist in his initial appeal provide no solid evidence that Gammagard works for the treatment of small fiber neuropathy. BMC's Senior Medical Director testified that there needs to be substantial evidence of safety and efficacy for a medication to be approved for treatment of a specific condition. BMC's Senior Medical Director testified further that the use of Gammagard to treat small fiber neuropathy would be considered experimental and investigational. BMC's Medical Director noted that Gammagard is not FDA approved for treatment of small fiber neuropathy. BMC's Medical Director noted further that small fiber neuropathy is not listed as a covered diagnosis in BMC HealthNet's Pharmacy Policy for IVIG, nor in MassHealth's Drug List for coverage of Gammagard. (Exhibit 10). BMC's Senior Medical Director pointed out that the appellant's request does not meet MassHealth criteria for coverage of Gammagard. (Exhibit 10).

The appellant's neurologist noted that in the past he has had success getting medications approved after a peer-to-peer review with BMC HealthNet physician reviewers, but did not have that opportunity for this request. The appellant's neurologist confirmed that the medical data as reported by BMC HealthNet is correct and the appellant was diagnosed with small fiber neuropathy as confirmed by a skin biopsy. The appellant's neurologist stated that although Gammagard is not FDA approved for treatment of small fiber neuropathy, he has had patients with small fiber neuropathy symptoms who trialed Gammagard with success. The appellant's neurologist stated that while he does not have experimental results to support this, IVIG treatment would get to the core of

the appellant's problem. The appellant's neurologist stated that alternative treatments only treat symptoms and do not address the diagnosis itself. The appellant's neurologist stated that it is not fair that the appellant be denied a trial of this medication when it makes sense from a clinical perspective and there is no alternative.

BMC's Associate General Counsel stated that all notices were sent timely to the appellant. BMC's Associate General Counsel noted further that no evidence in the form of clinical trials was presented to support the request for an off-label use of Gammagard and the appellant's neurologist provided only anecdotal support here.

Findings of Fact

Based on a preponderance of the evidence, I find the following:

1. The appellant is between the ages of 21 and 65 and is enrolled in BMC HealthNet's Well Sense ACO

2. The appellant's neurologist submitted a request for prior authorization for the prescription medication Gammagard liquid 10% vial to Express Scripts, BMC HealthNet's pharmacy benefit manager, on March 22, 2022, for treatment of the appellant's small fiber neuropathy.

3. Gammagard is an intravenous immune globulin (IVIG).

4. On March 23, 2022, Express Scripts denied the request for coverage of Gammagard because the appellant's diagnosis is not covered under BMC HealthNet's clinical criteria for coverage of Gammagard.

5. On March 23, 2022, the appellant's neurologist submitted an appeal, on behalf of the appellant, to BMC HealthNet.

6. On March 24, 2022, BMC HealthNet sent the appellant's case to an external, peer review neurologist for review and recommendation.

7. Based on a review of BMC HealthNet Well Sense Plan Pharmacy Policy for Immune Globulin, policy number 9.110, the peer review neurologist recommended denial of coverage of the Gammagard because the medication has not been determined medically necessary for the treatment of small fiber neuropathy.

8. On March 25, 2022, a BMC HealthNet physician reviewer, in consultation with the external peer review neurologist, denied the appeal of the denial of coverage for Gammagard because the appellant's diagnoses are not listed under the diagnoses, indications, and conditions approved for IVIG treatment under the BMC HealthNet's Pharmacy Policy.

9. By notice dated March 25, 2022, BMC HealthNet informed the appellant that the request for

Gammagard was denied because the appellant does not have a diagnosis approved for use of IVIG therapy and there is little significant clinical evidence of how well IVIG works in treating the appellant's condition.

10. The BMC HealthNet Pharmacy Policy sets forth the criteria necessary for coverage of IVIG medications, including Gammagard, at Policy Number 9.110.

11. The Policy notes that coverage of IVIG is recommended in patients who meet one of the 28 listed approved indications, diagnoses, and conditions.

12. Neither small fiber neuropathy nor fibromyalgia are listed as one of the 28 indications, diagnoses, or conditions for which Gammagard is approved.

13. The Policy notes that coverage is excluded when IVIG is prescribed for conditions in which there is insufficient clinical evidence to support its use.

14. Gammagard is not FDA approved for treatment of small fiber neuropathy.

Analysis and Conclusions of Law

Accountable Care Organization (ACO) – an entity that enters into a population-based payment model contract with EOHHS as an accountable care organization, wherein the entity is held financially accountable for the cost and quality of care for an attributed or enrolled member population. ACOs include Accountable Care Partnership Plans, Primary Care ACOs, and MCO administered ACOs. (130 CMR 610.004).

Mandatory Enrollment with a MassHealth Managed Care Provider. MassHealth members who are younger than 65 years old must enroll in a MassHealth managed care provider available for their coverage type. Members described in 130 CMR 508.001(B) or who are excluded from participation in a MassHealth managed care provider pursuant to 130 CMR 508.002(A) are not required to enroll with a MassHealth managed care provider. (130 CMR 508.001(A)).

Members are entitled to a fair hearing under 130 CMR 610.000: *MassHealth: Fair Hearing Rules* to appeal…

> (B) a determination by the MassHealth behavioral health contractor, by one of the MCOs, Accountable Care Partnership Plans, or SCOs as further described in 130 CMR 610.032(B), if the member has exhausted all remedies available through the contractor's internal appeals process…

130 CMR 508.010(B).

The appellant exhausted the internal appeal process offered through her ACO, and thus is entitled to a fair hearing pursuant to the above regulations. As MassHealth's agent, BMC HealthNet is required to follow MassHealth laws and regulations pertaining to a member's care. MassHealth requires prior authorization for the prescription medication Gammagard.

Service Limitations.
(1) MassHealth covers drugs that are not explicitly excluded under 130 CMR 406.413(B). The limitations and exclusions in 130 CMR 406.413(B) do not apply to medically necessary drug therapy for MassHealth Standard and CommonHealth enrollees under age 21. The MassHealth Drug List specifies those drugs that are payable under MassHealth. Any drug that does not appear on the MassHealth Drug List requires prior authorization, as set forth in 130 CMR 406.000. The MassHealth Drug List can be viewed online at www.mass.gov/druglist, and copies may be obtained upon request. *See* 130 CMR 450.303: *Prior Authorization*.
(2) The MassHealth agency does not pay for the following types of drugs, or drug therapies or non-drug products without prior authorization:

(a) immunizing biologicals and tubercular (TB) drugs that are supplied to the provider free of charge through local boards of public health or through the Massachusetts Department of Public Health (DPH); and

(b) any drug, drug therapy, or non-drug product designated in the MassHealth Drug List as requiring prior authorization.

(3) The MassHealth agency does not pay for any drug prescribed for other than the FDA-approved indications as listed in the package insert, except as the MassHealth agency determines to be consistent with current medical evidence.
(4) The MassHealth agency does not pay for any drugs that are provided as a component of a more comprehensive service for which a single rate of pay is established in accordance with 130 CMR 450.307: Unacceptable Billing Practices.

(130 CMR 406.413(C)).

The MassHealth Drug List specifies the drugs that are payable under MassHealth and designates which drugs require prior authorization. Any drug that does not appear on the MassHealth Drug List requires prior authorization. The MassHealth agency evaluates the prior authorization status of drugs on an ongoing basis and updates the MassHealth Drug List accordingly. (130 CMR 406.422(E)).

The MassHealth agency will not pay a provider for services that are not medically necessary and may impose sanctions on a provider for providing or prescribing a service or for admitting a member to an inpatient facility where such service or admission is not medically necessary.

(A) A service is "medically necessary" if:

(1) it is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member that endanger life, cause suffering or pain, cause physical deformity or malfunction, threaten to cause or to aggravate a handicap, or result in illness or infirmity; and

(2) there is no other medical service or site of service, comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly to the MassHealth agency. Services that are less costly to the MassHealth agency include, but are not limited to, health care reasonably known by the provider, or identified by the MassHealth agency pursuant to a prior-

authorization request, to be available to the member through sources described in 130 CMR 450.317(C), 503.007, or 517.007.

(B) Medically necessary services must be of a quality that meets professionally recognized standards of health care, and must be substantiated by records including evidence of such medical necessity and quality. A provider must make those records, including medical records, available to the MassHealth agency upon request. (See 42 U.S.C. 1396a(a)(30) and 42 CFR 440.230 and 440.260.)

(C) A provider's opinion or clinical determination that a service is not medically necessary does not constitute an action by the MassHealth agency.

(D) Additional requirements about the medical necessity of acute inpatient hospital admissions are contained in 130 CMR 415.414.

(130 CMR 450.204(A)-(D)).

The prescription medication Gammagard appears on the MassHealth Drug List as requiring prior authorization. (Exhibit 10, p. 1). The MassHealth Drug List sets forth the therapeutic uses and prior authorization criteria for Gammagard. (Exhibit 10).

Therapeutic Uses

FDA-approved, for example:

- Primary immunodeficiency disorder (e.g., primary/congenital agammaglobulinemia, severe combined immunodeficiency (SCID), Wiskott-Aldrich Syndrome, common variable immunodeficiency (CVID), hypogammaglobulinemia, X-linked agammaglobulinemia)
- Immune thrombocytopenia (ITP)
- Kawasaki disease (mucocutaneous lymph node syndrome)
- B-cell chronic lymphocytic leukemia (CLL)
- Chronic inflammatory demyelinating polyneuropathy (CIDP)
- Multifocal Motor Neuropathy (MMN)
- Dermatomyositis in adults (DM)

Note: The above list may not include all FDA-approved indications

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic,

the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All prior-authorization requests must include clinical diagnosis, drug name, dose, and frequency.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply, depending upon the member's condition and requested medication (see below).

Primary immunodeficiency disorders (Asceniv, Bivigam, Cutaquig, Cuvitru, Flebogamma, Gammagard, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Hizentra SC, Hyqvia, Octagam, Panzyga, Privigen, and Xembify)

- Documentation of the following is required:
    - laboratory documentation supporting diagnosis (e.g., deficient serum IgG [or subclasses IgG1, IgG2, IgG3, and IgG4], IgM, and/or IgA levels, assessment of functional antibody production, immunophenotype of B cells [flow cytometry] or genetic testing); and
    - Serum IgG (or subclasses IgG1, IgG2, IgG3, and IgG4), IgM, and/or IgA levels are provided via medical records or written on PA with dates drawn and reference ranges; and
    - dose is appropriate for the member and treatment course; and
    - for requests for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Immune thrombocytopenia (Flebogamma, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Octagam, Panzyga, and Privigen)

- Documentation of the following is required:
    - one of the following:
        - platelets < 30,000 /µL; or
        - clinically significant bleeding; or
        - history of significant bleeding; or
        - risk of significant bleeding; or
        - medical necessity to raise platelet count within 12 to 24 hours; and

    - dose is appropriate for member and treatment course; and
    - for requests for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Kawasaki disease (Gammagard S/D)

- Documentation of the following is required:
    - one of the following:
        - onset of illness occurred within previous 10 days; or
        - member has unexplained persistent fever; or
        - member has evidence of aneurysm; or
        - member exhibits signs of persistent inflammation; and
    - drug and dose are appropriate for the member and treatment course; and
    - for requests for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Multifocal Motor Neuropathy (Gammagard)

- Documentation of the following is required:
    - appropriate diagnosis; and
    - dose is appropriate for the member and treatment course; and
    - for requests for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Prevention of recurrent infection in B-cell chronic lymphocytic leukemia (Gammagard S/D)

- Documentation of the following is required:
    - appropriate diagnosis; and
    - dose is appropriate for member and treatment course; and
    - for requests for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

(MassHealth Drug List, exhibit 10).

The appellant's diagnoses of small fiber neuropathy and fibromyalgia do not appear on the MassHealth Drug List under diagnoses for which there is FDA approval for Gammagard, nor do the appellant's diagnoses appear under the MassHealth's Drug List's Evaluation Criteria for approval of Gammagard. (Exhibit 10). Because the appellant does not meet the prior authorization criteria for coverage of Gammagard pursuant to MassHealth regulations, Gammagard would not be approved for the appellant by MassHealth.

BMC HealthNet's Pharmacy Policy sets forth BMC HealthNet's criteria for coverage of Gammagard. (Exhibit 9, pp. 49-73). BMC HealthNet's Pharmacy Policy 9.110 lists the FDA approved indications for IVIG as follows:

Primary Immunodeficiencies (PID); B-Cell Chronic Lymphocytic Leukemia (CLL) for Prevention of Bacterial Infections; Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) or Polyradiculoneuropathy; Idiopathic (Immune) Thrombocytopenic Purpura (ITP) or Immune Thrombocytopenia (IT), Acute and Chronic; Kawasaki Disease; Multifocal Motor Neuropathy (MMN) (Treatment).

Other Uses with Supportive Evidence

Antibody-Mediated Rejection (AMBR) in Solid Organ Transplant (e.g., Kidney, Heart, Lung, Liver); Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita); Cytomegalovirus (CMV) Interstitial Pneumonia in Patients with Cancer or Transplant-Related Infection; Dermatomyositis or Polymyositis; Desensitization Therapy Prior to and Immediately after Solid Organ (Kidney, Heart, Lung, Liver, Intestinal) Transplantation; Guillain Barré Syndrome (GBS); Hematologic Neoplasm-Associated Hypogammaglobulinemia or Hypogammaglobulinemia after B-cell Targeted Therapies (Secondary Immunodeficiency [SID]); Hematopoietic Cell Transplantation (HCT) to Prevent Bacterial Infection; Human Immunodeficiency Virus (HIV)-Associated Thrombocytopenia; Human Immunodeficiency Virus (HIV)-Infected Infants and Children to Prevent Recurrent Bacterial Infections; Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitor Therapy; Lambert-Eaton Myasthenic Syndrome (LEMS); Multiple Myeloma; Multiple Sclerosis (MS), Acute Severe Exacerbation or Relapses; Multiple Sclerosis (MS), Post-Partum to Prevent Relapses; Myasthenia Gravis; Passive Immunization for Measles (Post-Exposure Prophylaxis); Passive Immunization for Varicella (Chickenpox) [Post-Exposure Prophylaxis]; Pure Red Blood Cell Aplasia (PRCA) Secondary to Chronic (Persistent) Parvovirus B19 Infection; Pure Red Blood Cell Aplasia (PRCA), Immunologic Subtype; Stiff-Person Syndrome (Moersch-Woltman Syndrome); Thrombocytopenia, Feto-neonatal Alloimmune.

(Exhibit 10, pp. 50-59).

BMC HealthNet Pharmacy Policy Number 9.110 lists the following under EXCLUSION CRITERIA for IVIG:

When immune globulin is prescribed for condition(s) in which there is insufficient clinical evidence to support its use and/ or if the request is for one for the following:

.• Adrenoleukodystrophy • Alzheimer's Disease (AD) • Amyotrophic Lateral Sclerosis • Anemia, Aplastic • Asthma • Atopic Dermatitis • Autism • BK Virus Associated Nephropathy (BKVAN) in Kidney Transplant Patient • Chronic Fatigue Syndrome • Chronic Myasthenia Gravis • Complex Regional Pain Syndrome (Reflex Sympathetic Dystrophy) • Crohn's Disease • Cystic Fibrosis • Cytomegalovirus (CMV) Disease Prophylaxis in Hematopoietic Cell Transplantation [HCT] Recipients • Cytomegalovirus (CMV) Infection, Preemptive Therapy for Cytomegalovirus [CMV] Infection or Treatment of Cytomegalovirus {CMV} Disease, in Allogeneic Hematopoietic Cell Transplantation (HCT) Recipients • Cytomegalovirus (CMV)

Infections, Prophylaxis or Treatment in Solid Organ Transplantation, (e.g., Heart, Kidney) for Prophylaxis • Diabetes Mellitus, Immunotherapy • Epilepsy, Pediatric Intractable • Fibromyalgia Syndrome • Graft Versus Host Disease (GVHD), Acute [Within First 100 days After Hematopoietic Cell Transplantation {HCT}] • Graft Versus Host Disease (GVHD), chronic, Prevention in Hematopoietic Cell Transplantation [HCT] Recipient • Heart Block, Congenital (Prevention) • Heart Failure, Chronic • Hematopoietic Cell Transplantation (HCT) in Allogeneic Recipients from Human Leukocyte Antigen [HLA]-Identical Sibling Donors • Human Immunodeficiency Virus (HIV) Infection, Adults, for Prophylaxis of Infections • Immune Globulin M (IgM) Paraproteinemic Demyelinating Neuropathy [or Other Paraproteinemic Demyelinating Neuropathies] • In Vitro Fertilization (IVF) • Infantile Spasms (West Syndrome) • Marburg Variant Multiple Sclerosis (MS) • Multiple Sclerosis (MS), Primary or Secondary Progressive, Relapsing Remitting for the Prevention of Relapses • Nephropathy, Membranous • Organomegaly, Endocrinopathy, Monoclonal Gammopathy, and Skin Changes (POEMS) Syndrome • Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection (PANDAS) • Post-Polio Syndrome • Recurrent Spontaneous Pregnancy Loss (RSPL) [Including Antiphospholipid Antibody-Positive Women] • Selective Immune Globulin A (IgA) Deficiency as the Sole Immunologic Abnormality • Systemic Lupus Erythematosus (SLE) • Systemic Sclerosis (Scleroderma) • Thrombocytopenia, Heparin-Induced (HIT) • Thrombotic Thrombocytopenic Purpura (TTP)/Hemolytic Uremic Syndrome (HUS) • Urticaria, Chronic Autoimmune • Uveitis, Noninfectious.

(Exhibit 10, pp. 60-61).

The appellant's diagnosis of small fiber neuropathy is not listed under FDA approved indications, nor under "other uses with supportive evidence" in the BMC Health Net's Pharmacy Policy for coverage of Gammagard, and the appellant's diagnosis of fibromyalgia is listed under the Policy's Exclusion criteria for IVIG. (Exhibit 10, pp. 50-61). The Policy notes further that when IVIG is prescribed for conditions in which there is insufficient clinical evidence to support its use, it is excluded from coverage. (Exhibit 10, pp. 60-61).

Because the appellant does not have a diagnosis, indication, or condition listed in the MassHealth Drug List or in the BMC HealthNet's Pharmacy Policy to be considered for approval of coverage for Gammagard, the request does not satisfy the prior authorization requirements for MassHealth coverage nor does it meet the medical necessity criteria for BMC HealthNet coverage. BMC HealthNet's denial of the appellant's internal appeal is upheld and the appellant's appeal is denied.

Order for ACO

None.

Notification of Your Right to Appeal to Court

If you disagree with this decision, you have the right to appeal to Court in accordance with Chapter 30A of the Massachusetts General Laws. To appeal, you must file a complaint with the Superior Court for the county where you reside, or Suffolk County Superior Court, within 30 days of your receipt of this decision.

Patricia Mullen
Hearing Officer
Board of Hearings

cc: MassHealth Representative: BMC HealthNet Plan, Member Appeals & Grievances, Attn: Felicia Hughes, 529 Main Street, Ste. 500, Charlestown, MA 02129