

Intravenous Immune Globulin (IVIG)

Alyglo, Asceniv, Bivigam, Cutaquig, Cuvitru, Flebogamma, Gammagard Liquid, Gammagard S/D, Gammagard ERC, Gammaked, Gammaplex, Gamunex-C, Hizentra, Hyqvia, Octagam, Panzyga, Privigen, Xembify, Qivigy, Yimmugo
Effective 10/01/2026

Plan	☒ MassHealth UPPL ☐ Commercial/Exchange		Program Type	☒ Prior Authorization
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit			☐ Quantity Limit ☐ Step Therapy
Specialty Limitations	N/A			
Contact Information	Medical Benefit	Phone: 833-895-2611	Fax: 888-656-6671	
	Pharmacy Benefit	Phone: 800-711-4555	Fax: 844-403-1029	
Notes	These agents are also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.			

Overview

IVIG is replacement therapy for primary and secondary immunodeficiencies, and IgG antibodies against bacteria, viral, parasitic and mycoplasma antigens; interference with Fc receptors on the cells of the reticuloendothelial system for autoimmune cytopenia and ITP; provides passive immunity by increasing the antibody titer and antigen-antibody reaction potential.

FDA-Approved Indications

Formulation	Route of Administration	CLL	CIDP	DM	ITP	KD	MMN	PID
Alyglo	IV							✓
Asceniv	IV							✓
Bivigam	IV							✓
Cutaquig	SC							✓
Cuvitru	SC							✓
Flebogamma 10%	IV				✓			✓
Flebogamma 5%	IV				✓			✓
Gammagard (IgA~37mcg/mL)	IV, SC*		✓				✓	✓
Gammagard ERC (IgA~2mcg/mL)	IV, SC*							✓
Gammagard S/D (IgA<1 mcg/mL)	IV	✓			✓	✓		✓
Gammaked	IV, SC*		✓		✓			✓
Gammaplex	IV				✓			✓
Gamunex -C	IV, SC*		✓		✓			✓
Hizentra	SC		✓					✓
Hyqvia	SC		✓					✓

Octagam 10%	IV			✓†	✓†			
Octagam 5%	IV							✓‡
Panzyga	IV		✓		✓			✓
Privigen	IV		✓		✓			✓
Qivigy	IV							✓
Xembify	SC							✓
Yimmugo	IV							✓

* Subcutaneous route is only indicated for PID

† Octagam 10% strength approved for chronic ITP in adults and DM in adults

‡ Octagam 5% strength approved for PID

§ Gamastan® S/D approved for prophylaxis following exposure to hepatitis A, to prevent or modify measles in a susceptible person exposed fewer than 6 days previously, to modify varicella, and to modify rubella in exposed women who will not consider a therapeutic abortion.

Coverage Guidelines

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for members when following criteria are met, and documentation is provided:

IV and SC Immune Globulins (except Gamastan S/D)

Chronic inflammatory demyelinating polyneuropathy (CIDP)

1. Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP)
2. Prescriber is a specialist (e.g. neurologist or immunologist) or consult notes from specialist are provided
3. **ONE** of the following:
 - a. Requested IVIG dose is ≤ 2 g/kg in divided doses for loading doses and up to 1 g/kg in divided doses every 3 weeks for maintenance dosing
 - b. Medical necessity for a higher dose (e.g. disease severity, dose titrated based on previous response to therapy)

Multifocal Motor Neuropathy (MMN)

1. Diagnosis of multifocal motor neuropathy (MMN)
2. Prescriber is a specialist (e.g. neurologist) or consult notes from specialist are provided
3. **ONE** of the following:
 - a. Requested IVIG dose is ≤ 2.4 g/kg in divided doses every 4 weeks

Medical necessity for a higher or more frequent dose (e.g., disease severity, frequency of relapses, etc.)

Immune thrombocytopenia (ITP)

1. Diagnosis of immune thrombocytopenia (ITP)
2. Prescriber is a specialist (e.g. hematologist) or consult notes from specialist are provided
3. **ONE** of the following:
 - a. Platelets $< 30,000 /\mu\text{L}$
 - b. Clinically significant bleeding
 - c. History of significant bleeding
 - d. Risk of significant bleeding



- e. Medical necessity to raise platelet count within 12 to 24 hours
- 4. **ONE** of the following:
 - a. Requested IVIG dose is ≤ 1 g/kg daily for 2 days or 0.4 g/kg daily for 5 days
 - b. Medical necessity for a higher or more frequent dose (e.g., disease severity, life threatening bleeding, etc.)

Kawasaki disease (mucocutaneous lymph node syndrome)

- 1. Diagnosis of Kawasaki disease (mucocutaneous lymph node syndrome)
- 2. Prescriber is a specialist (e.g. cardiologist or rheumatologist) or consult notes from specialist are provided
- 3. **ONE** of the following:
 - a. Onset of illness occurred within previous 10 days
 - b. Unexplained persistent fever
 - c. Evidence of aneurysm
 - d. Signs of persistent inflammation
- 4. **ONE** of the following:
 - a. Requested IVIG dose is ≤ 2 g/kg given as a single dose or 0.4 g/kg daily for 4 days
 - b. Medical necessity for a higher or more frequent dose (e.g., disease severity, persistent fever, etc.)

Primary Immunodeficiency Disorders (PID)

- 1. Diagnosis of primary immunodeficiency disorder (PID)
- 2. Prescriber is a specialist (e.g. immunologist) or consult notes from specialist are provided
- 3. Laboratory documentation supporting diagnosis (e.g. deficient serum IgG [or subclasses IgG1, IgG2, IgG3, IgG4], IgM, and/or IgA levels, assessment of functional antibody production, immunophenotype of B cells [flow cytometry] or genetic testing)
- 4. Serum IgG (or subclasses IgG1, IgG2, IgG3, IgG4), IgM, and/or IgA levels are provided via medical records or written on PA with dates drawn and reference ranges (e.g., pre- or post-treatment)
- 5. **ONE** of the following:
 - a. Requested IVIG dose is ≤ 0.8 g/kg every 3 to 4 weeks
 - b. Medical necessity for a higher or more frequent dose (e.g., severe or recurrent infections despite standard dosing, dose adjustment for a targeted IgG trough level, etc.)

Autoimmune Blistering Disorders (AIBD)

- 1. Diagnosis of **ONE** of the following:
 - a. Bullous pemphigoid
 - b. Epidermolysis bullosa acquisita (EBA)
 - c. Mucous membrane pemphigoid (MMP)
 - d. Paraneoplastic pemphigus (PNP)
 - e. Pemphigus vulgaris (PV)
- 2. Diagnosis of moderate to severe disease (e.g. extensive skin involvement, mucosal disease, or rapid progression)
- 3. Prescriber is a specialist (e.g. dermatologist) or consult notes from specialist are provided
- 4. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** systemic corticosteroids
- 5. Inadequate response, adverse reaction, or contraindication to rituximab
- 6. **ONE** of the following
 - a. Requested IVIG dose is ≤ 2 g/kg divided over 2 to 5 days every 4 weeks



- b. Medical necessity for a higher or more frequent dose (e.g., ocular or oral pemphigoid, severe or rapidly progressing disease despite standard doses, etc.)

Antibody Mediated Rejection (AMR)

1. Diagnosis of AMR
2. Prescriber is a specialist (e.g. transplant specialist) or consult notes from specialist are provided
3. **ONE** of the following
 - a. Requested IVIG dose is ≤ 2 g/kg in divided doses every 4 weeks
 - b. Medical necessity for a higher or more frequent dose (e.g., disease severity, dosing per institutional protocol, etc.)

Autoimmune Encephalitis (Includes NMDA-receptor encephalitis)

1. Diagnosis of autoimmune encephalitis or anti-NMDA receptor encephalitis
2. Prescriber is a specialist (e.g. neurologist) or consult notes from specialist are provided
3. **ONE** of the following:
 - a. Requested IVIG dose is ≤ 2 g/kg/day divided over two to five days, followed by 1 g/kg once monthly
 - b. Medical necessity for a higher or more frequent dose (e.g., severe or rapidly progressive disease, inadequate response to standard dosing, etc.)

Autoimmune Small Fiber Neuropathy and Autoimmune autonomic ganglionopathy (AAG)

1. Diagnosis of Autoimmune Small Fiber Neuropathy or AAG
2. Prescriber is a specialist (e.g. neurologist) or consult notes from specialist are provided
3. **ONE** of the following:
 - a. Requested IVIG dose is ≤ 2 g/kg in divided doses every four weeks
 - b. Medical necessity for a higher or more frequent dose (e.g., severe or rapidly progressive disease, significant functional impairment, inadequate response to standard dosing, etc.)

BK Polyomavirus-Associated Nephropathy (BKPyVAN)

1. Diagnosis of BK polyomavirus-associated nephropathy (BKPyVAN)
2. Prescriber is a specialist (e.g. transplant or infectious disease specialist) or consult notes from specialist are provided
3. **ONE** of the following
 - a. Persistent viremia despite a reduction in baseline immunosuppressive regimen
 - b. High risk for rejection or unable to reduce immunosuppressive regimen
 - c. Hypogammaglobulinemia (IgG < 400 mg/dL)
4. **ONE** of the following:
 - a. Requested IVIG dose is ≤ 2 g/kg in divided doses every 4 weeks
 - b. Medical necessity for a higher or more frequent (e.g., disease severity, persistent or rising viral load, decline in graft function, etc.)

Guillain-Barré Syndrome (GBS)

1. Diagnosis of Guillain-Barré Syndrome (GBS)
2. Prescriber is a specialist (e.g. neurologist) or consult notes from specialist are provided
3. Requested IVIG dose is ≤ 2 g/kg in divided doses

Prevention of Recurrent Infections in Oncology-Related Immunodeficiency

1. Prevention of recurrent infections with **ONE** of the following:



- a. Diagnosis of a hematologic malignancy (e.g., B-cell chronic lymphocytic leukemia [CLL], multiple myeloma [MM], other B-cell malignancies, etc.)
 - b. Post CAR T-cell therapy
 - c. Post hematopoietic stem cell transplant (HSCT)
2. Prescriber is a specialist (e.g., hematologist or oncologist) or consult notes from specialist are provided
3. **ONE** of the following:
 - a. Hypogammaglobulinemia (IgG <400 mg/dL)
 - b. Recurrent infections despite prophylactic antibiotics
4. **ONE** of the following:
 - a. Requested IVIG dose $\leq$ to 0.4 to 0.6 g/kg every 3 to 4 weeks
 - b. Medical necessity for a higher or more frequent dose (e.g., severe or persistent hypogammaglobulinemia or increased frequency or severity of infections despite standard dose, etc.)

Immune Neutropenia (autoimmune neutropenia (AIN), Chronic benign neutropenia)

1. Diagnosis of immune neutropenia (autoimmune neutropenia (AIN), Chronic benign neutropenia)
2. Prescriber is a specialist (e.g. hematologist) or consult notes from specialist are provided
3. Recurrent infections despite prophylactic antibiotics
4. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** granulocyte colony stimulating factors (G-CSFs)
5. **ONE** of the following
 - a. Requested IVIG dose is $\leq$ 2 g/kg in divided doses every 4 weeks
 - b. Medical necessity for a higher or more frequent dose (e.g., severe neutropenia, increased frequency or severity of recurrent infections despite standard dose, etc.)

Myasthenia Gravis (MG)

1. Diagnosis of myasthenia gravis
2. Prescriber is a specialist (e.g. neurologist) or consult notes from specialist are provided
3. **ONE** of the following:
 - a. Severe or rapidly worsening disease, and IVIG will be used as initial therapy followed by longer acting immunomodulating agents (e.g., azathioprine, cyclosporine, mycophenolate, corticosteroids)
 - b. Inadequate response, adverse reaction, or contraindication to **ALL** of the following:
 - i. pyridostigmine
 - ii. systemic corticosteroids
 - iii. one immunomodulating agent (e.g., azathioprine, cyclosporine, mycophenolate)
4. **ONE** of the following:
 - a. Requested IVIG dose is $\leq$ 2 g/kg divided over 2 to 5 days followed by 1 g/kg every 3 to 4 weeks
 - b. Medical necessity for a higher or more frequent dose (e.g., increased frequency of relapses or flares, need for shorter dosing interval to maintain symptom control, etc.)

Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS)

1. Diagnosis of PANDAS
2. Prescriber is a specialist (e.g. pediatrician or neurologist) or consult notes from specialist are provided
3. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** antibiotics
4. Inadequate response or adverse reaction to **ONE** or contraindication **ALL** to systemic corticosteroids
5. **ONE** of the following
 - a. Requested IVIG dose is $\leq$ 2 g/kg divided over 2 days, followed by 1 to 2 g/kg every 4 to 6 weeks



- b. Medical necessity for a higher or more frequent dose (e.g., recurrent or relapsing neuropsychiatric flares, severe functional impairment, etc.)

Idiopathic Inflammatory Myopathies/Myositis (IIM)

1. Diagnosis of **ONE** of the following:
 - a. Anti-synthetase syndrome (ASyS)
 - b. Dermatomyositis (DM)
 - c. Immune-mediated necrotizing myopathy/myositis (IMNM)
 - d. Myositis with connective tissue disorder overlap (e.g., systemic sclerosis [SSc] myositis or SLE-myositis)
 - e. Polymyositis (PM)
2. Prescriber is a specialist (e.g. neurologist or rheumatologist) or consult notes from specialist are provided
3. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** systemic corticosteroids
4. **ONE** of the following:
 - a. Diagnosis of severe disease (e.g., dysphagia due to muscle weakness, calcinosis cutis, myositis associated with inflammatory lung disease [ILD], anti-HMGCR positive IMNM, significant functional impairment, or rapidly progressive weakness, etc.)
 - b. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following
 - i. azathioprine
 - ii. calcineurin inhibitor (CNI)
 - iii. cyclophosphamide
 - iv. methotrexate
 - v. mycophenolic acid analog (MPAA)
 - vi. rituximab
 - vii. tacrolimus
5. **ONE** of the following:
 - a. Requested IVIG dose of ≤ 2 g/kg divided over 2 to 5 days every 4 weeks
 - b. Medical necessity for a higher or more frequent dose (e.g., severe and progressive weakness or functional impairment, disease relapses despite standard dose, etc.)

Localized Scleroderma

1. Diagnosis of **ONE** of the following:
 - a. Linear scleroderma
 - b. Juvenile localized scleroderma
 - c. Morphea
2. Prescriber is a specialist (e.g. dermatologist or rheumatologist) or consult notes from specialist are provided
3. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** systemic corticosteroids
4. **ONE** of the following:
 - a. Diagnosis of severe disease (e.g., scleroderma involving deep tissue or crossing a joint, craniofacial involvement, etc.)
 - b. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following
 - i. azathioprine
 - ii. cyclophosphamide
 - iii. methotrexate
 - iv. mycophenolic acid analog (MPAA)
 - v. rituximab



5. **ONE** of the following:
 - a. Requested IVIG dose of ≤ 2 g/kg in divided doses every 4 weeks
 - b. Medical necessity for a higher or more frequent dose (e.g. new lesions or disease progression despite standard dose, severe functional impairment, etc.)

Prevention of recurrent infection in pediatric HIV members

1. Diagnosis of human immunodeficiency virus (HIV)
2. Prescriber is a specialist (e.g. infectious disease specialist) or consult notes from specialist are provided
3. Member is < 18 years of age
4. **ONE** of the following:
 - a. Hypogammaglobulinemia (IgG < 400 mg/dL)
 - b. Recurrent infections despite antibacterial prophylaxis
5. **ONE** of the following:
 - a. Requested IVIG dose is ≤ 0.4 g/kg every four weeks
 - b. Medical necessity for a higher or more frequent dose (e.g., increased frequency or severity of infections, etc.)

Cytomegalovirus (CMV)

1. Diagnosis of cytomegalovirus (CMV)
2. Prescriber is a specialist (e.g. transplant, hematologist, oncologist, or infectious disease specialist) or consult notes from specialist are provided
3. Requested agent will be used in combination with ganciclovir, foscarnet, or cidofovir, or valganciclovir (at treatment dose)
4. **ONE** of the following
 - a. Severe or refractory disease (e.g., tissue invasive disease [pneumonitis, colitis, hepatitis, retinitis], persistent viremia despite treatment, etc.)
 - b. Hypogammaglobulinemia (IgG <400 mg/dL) or rapidly declining IgG levels post-transplant
5. **ONE** of the following:
 - a. Requested IVIG dose ≤ 2 g/kg in divided doses every 4 weeks
 - b. Medical necessity for a higher or more frequent dose (e.g., severe or rapidly progressive disease, dose adjustment for a targeted IgG trough level, inadequate response to standard dosing, etc.)

Selective Antibody Deficiency (SAD)

1. Diagnosis of selective antibody deficiency (SAD) , including specific pneumococcal antibody deficiency or selective antibody deficiency with normal immunoglobulins (SADNI)
2. Moderate or severe polysaccharide nonresponsiveness (e.g., failure to respond to ≥ 50 –70% of serotypes after pneumococcal vaccination)
3. Prescriber is a specialist (e.g. immunologist) or consult notes from specialist are provided
4. Evidence of recurrent infections requiring antibiotic therapy
5. **ONE** of the following:
 - a. Requested IVIG dose of ≤ 0.4 to 0.6 g/kg every 4 weeks
Medical necessity for a higher or more frequent dose (e.g., increased frequency or severity of infections despite standard dose, etc.)

Stiff Person Syndrome (SPS)



1. Diagnosis of SPS
2. Prescriber is a specialist (e.g. neurologist) or consult notes from specialist are provided
3. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** benzodiazepines
4. Inadequate response, adverse reaction, or contraindication to baclofen
5. **ONE** of the following:
 - a. Requested IVIG dose is ≤ 2 g/kg, divided over 3 to 5 days every 4 weeks
 - b. Medical necessity for a higher or more frequent dose (e.g., frequency of muscle spasms, severe disease affecting ambulation or posture, etc.)

Gamastan S/D (immune globulin IM, human)

1. **ONE** of the following:
 - a. Use for protection against Hepatitis A virus in an unvaccinated member who has been exposed to the virus in the previous 2 weeks **OR** cannot receive hepatitis A vaccine (i.e., hypersensitivity or child less than one year of age)
 - b. Use to prevent or modify symptoms of measles if exposed within the past 6 days
 - c. Use for passive immunization against varicella in immunosuppressed member when Varicella-Zoster Immune Globulin (human) is not available
 - d. Use for postexposure prophylaxis of rubella in a pregnant member
2. Appropriate dosing for member and diagnosis (see appendix)

If a request for subcutaneous immune globulin without prior IVIG use is submitted, please refer to Appendix.

Continuation of Therapy

Reauthorizations for continuation of therapy may be issued for up to **1 year** or as appropriate for the diagnosis provided:

- **AIBD, CIDP, IIM, localized scleroderma, MMN, PID:** Resubmission by prescriber will infer a positive response to therapy.

Reauthorizations for continuation of therapy may be issued for up to **6 months** or as appropriate for the diagnosis provided:

- **Prevention of recurrent infection in oncology-related immunodeficiency and pediatric HIV:** Prescriber provides documentation of continued need for infection protection and a positive response to previous therapy.
- **All other indications:** Prescriber provides documentation of continued medical necessity and a positive response to therapy.

Reauthorizations for continuation of therapy may be issued for up to **1 month** or as appropriate for the diagnosis provided:

- **ITP:** Prescriber provides documentation or laboratory results supporting continued use (*e.g. platelets < 30,000 / μ L and/or has clinically significant bleeding, history of or risk of significant bleeding, medical necessity to raise platelet count within 12 to 24 hours*)
- **Gamastan S/D:** Prescriber provides documentation of medical necessity for continued use.

Limitations

1. Initial approvals will be granted for the following indications:
 - a. Kawasaki Disease, Gamastan S/D, BKPvYAN, GBS, ITP: 1 month
 - b. AIBD, CIDP, IIM, localized scleroderma, MMN, PID: 6 months



- c. All other indications: 3 months
2. Reauthorization approval durations are listed within the criteria above.
 - a. Reauthorizations for Kawasaki Disease will be reviewed against the initial criteria.
 - b. Reauthorizations for Guillain-Barré Syndrome: Re-treatment is not recommended.
3. Please note that dosing in certain off-label indications is not well established. Unless otherwise specified within the approval criteria for an off-label indication, please refer to the FDA-approved label.

Appendix

Subcutaneous Immune Globulin in Treatment Naïve Members

If a request for subcutaneous immune globulin is received for a member without prior intravenous use, please review request for appropriate dosing (should be equal to IVIG or up to 1.5 times higher depending on the product). If the dosing is appropriate, requests may be approved for **6 months**.

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Review History

12/18/2019 – Reviewed and approved DCC

03/18/2020 – Transitioned from SGM to Custom (effective 6/1/20)

05/19/2021 – References updates

09/22/2021 – Reviewed at September P&T; added PANDA/PANS indication effective 01/01/2022; references updated. Effective 01/01/2022

02/08/2023 - Reviewed and updated for Feb P&T. Matched MH UPPL criteria to be in compliance with Masshealth unified formulary requirements. Removed Carimmune as product has been discontinued. Added Cutaquig, Cuvitru, Gamastan S/D, Hizentra, Hyqvia, Xembify. Effective 4/1/23.

05/10/23 – Reviewed and updated for P&T. Added off-label indications to policy: Antibody mediated rejection (AMR), Immune-mediated necrotizing myopathy (IMNM), Interstitial Lung Disease (ILD), Pemphigus Vulgaris (PV), Polymyositis (PM), and Prevention of recurrent infection in pediatric HIV members. Approval duration for off label indications except PANDAS were added. Appendix for Gamastan S/D dosing was added. Effective 6/5/23.

06/14/23 – Reviewed and updated for P&T. Removed preferred product requirement for requests through MB. Effective 6/30/23



08/09/23 – Reviewed and updated for P&T. Stability section updated to allow the approval of requests documenting positive response to therapy and to remove the requirement for the documentation of current labs showing normal Ig levels. Formatting updates. Effective 10/2/23.

09/11/24 – Reviewed and updated for P&T. Separated all agents in this class from pharmacy, 2 policies will now exist (MB and PB). Guideline updated with expanded indication for HyQvia and Gammagard in CIDP and for Flebogamma 5% in ITP. New intravenous immune globulin Alyglo was added to criteria and to require clinical rationale for use of this product over alternatives. Effective 10/1/24

08/13/25 – Reviewed and updated for P&T. Part of UM annual review. Formatting and reference updates made. Effective 9/1/25

11/12/25 – Reviewed and updated for P&T. Removed Gamastan S/D as product has been discontinued. Effective 1/1/26

03/11/26 – Reviewed and updated for P&T. Added new formulation of Gammagard ERC. Effective 3/9/26

4/15/26 - Initial and reauth approval durations for PANDAS was updated to 3 and 6 months, respectively. Criteria for specialist involvement was added for all indications. Effective 4/20/26

09/10/26 – Reviewed and updated for P&T. Qivigy and Yimmugo were added to the MB guideline requiring PA. Criteria update to all indications (except for GBS) to include appropriate dosing or medical necessity for higher doses. The following off-label indications were added: autoimmune blistering disorders, BK polyomavirus-associated nephropathy, idiopathic inflammatory myopathies/myositis, localized scleredema, prevention of recurrent infections in oncology-related immunodeficiency. Criteria updates were made to the following to better align IVIG place in therapy and streamline existing criteria: AMR, CMV, immune neutropenia, prevention of recurrent infections in pediatric HIV, and SAD. Individual criteria for the following indications was removed (included in new grouped indications): prevention of recurrent infection in B-cell CLL, MM, DM, IMNM, PM, ILD, and PV. Initial and reauthorization approval durations were updated for further clarification. Formatting and reference updates made. Effective 10/1/26

