Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 4.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Intravenous Immune Globulin (IVIG)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare		ACA	X
CHIP	X		

I. Policy:
Intravenous Immune Globulin (IVIG)

II. Purpose/Objective:
To provide a policy of coverage regarding Intravenous Immune Globulin (IVIG)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Immune Serum Globulins are used to provide passive immunity or to alter the immune response by increasing the recipients' antibody titer and antigen-antibody reaction potential. IgG antibodies help to prevent or modify certain infectious diseases in susceptible individuals. Five major classes of immunoglobulin proteins exist in human serum and other body fluids (IgA, IgD, IgE, IgG, and IgM). Immune globulin is an antibody-containing solution obtained from the pooled plasma of pre-screened, presumably healthy blood donors. Throughout the policy, the term "intravenous immune globulin" and "IVIG" is intended to refer to all immune globulin injections, including intravenous, intramuscular and subcutaneous administrations.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

This policy refers to the following intravenous immune globulin drug products:

Alyglo	Gammaked
Asceniv	Gammaplex
Bivigam	Gamunex
Carimune NF	Gamunex-C
Cutaquig	Hizentra
Cuvitru	Hyqvia
Flebogamma	Octagam
Flebogamma DIF	Panzyga
Gammagard Liquid	Privigen
Gammagard S/D	Xembify

IVIG is considered to be medically necessary for the Commercial, Exchange, CHIP and Medicaid lines of business for the following, however not limited to, indications when specified criteria are met (Note: The Medicare line of business is reviewed according to Centers for Medicare and Medicaid Services [CMS] Local Coverage Determination [LCD]):

- **Primary Humoral Immunodeficiencies, including combined immunodeficiencies**
  Congenital Agammaglobulinemia (X-linked agammaglobulinemia, Bruton's disease)
  Autosomal recessive agammaglobulinemia
  Common Variable Immunodeficiency (CVID)
  Wiskott-Aldrich Syndrome
  X-linked or autosomal recessive immunodeficiency with hyperimmunoglobulin M
  Severe Combined Immunodeficiency (SCID)
  Ataxia-telangectasia
  DiGeorge syndrome
  Nijmegen breakage syndrome
  Gruscelli syndrome
  NEMO deficiency
  WHIM (warts, hypogammaglobulinemia, immunodeficiency, and myelokathexis) syndrome
  X-linked lymphoproliferative disease (in patients with hypogammaglobulinemia or dysgammaglobulinemia and infections)
  Hypogammaglobulinemia provided the appropriate work up is performed to determine extent (ex. flow cytometry and anamnestic response to recall antigens)

  Patients with primary immunodeficiencies must meet the following criteria:
  1. Medical record documentation/laboratory results of immunoglobulin deficiency **AND**
  2. Medical record documentation of an inability to amount an adequate immunologic response to inciting antigens **AND**
  3. Medical record documentation of persistent and severe infections

- **Idiopathic Thrombocytopenia Purpura (ITP)**
  1. Acute ITP when one of the following are present:
     - Active bleeding and a platelet count of less than 30,000/mm^3 **or** documented history of significant bleeding and a platelet count of less than 30,000/mm^3 **AND**
     - Medical record documentation of use in conjunction with a corticosteroid or a contraindication to or failure on corticosteroid therapy

     OR

     - As a preoperative treatment prior to major invasive surgical procedures **AND**
     - IVIG be used with corticosteroids when a more rapid increase in platelet count is required

     OR

     - A platelet count of less than 20,000/mm^3 **AND**
     - Medical record documentation of use in conjunction with a corticosteroid or a contraindication to or failure on corticosteroid therapy

  2. Chronic ITP when one of the following criteria are met:
     - Duration of Immune Thrombocytopenia (ITP) greater than 12 months **AND**
     - No concurrent illness or disease explaining thrombocytopenia **AND**
     - Medical documentation of prior treatment with corticosteroids (ex, prednisone 2 mg/kg/day for ≤ 6 weeks (for adults) or 4 mg/kg/day for ≤ 7 days (for children)); AND a splenectomy, if over 12 months have elapsed from date of initial diagnosis
       OR
     - Active bleeding and a platelet count of less than 30,000/mm^3 **or** documented history of significant bleeding and a platelet count of less than 30,000/mm^3
       OR
     - A platelet count of less than 20,000/mm^3
       OR
     - As a preoperative treatment prior to major invasive surgical procedures

  3. ITP in pregnancy with medical documentation of the following:
     - One of the following:
       - Active bleeding and a platelet count of less than 30,000/mm^3; or documented history of significant bleeding and a platelet count of less than 30,000/mm^3 **OR**
       - A platelet count of less than 20,000/mm^3 **OR**
       - Intent to increase platelet counts to a level considered safe for procedures

       AND
     - A contraindication to, intolerance to or therapeutic failure on corticosteroid therapy OR a more rapid increase in platelets is necessary, as determined by the prescriber*

     *Note: initial response to corticosteroids usually occurs within 4-14 days and reaches a peak response within 1-4 weeks. Initial response to IVIG usually occurs within 1-3 days and reaches a peak response within 2-7 days.

  4. Secondary ITP
     - *H-pylori*-associated
       - Eradication of H-pylori in patients testing positive

- **Acquired Hypogammaglobulinemia Secondary to Chronic B-cell Lymphocytic Leukemia or Multiple Myeloma**
  The following criteria must be met:
  1. IgG less than 500 mg/dl **AND**
  2. a documented history of repeated bacterial infection two times in one year or a severe bacterial infection within the last 6 months

- **Post-transfusion purpura**
  The following criteria must be met:
  1. Medical record documentation of an onset of severe thrombocytopenia (platelet count less than 30,000/mm3) occurring 2-14 days post blood product transfusion.

- **Kawasaki Disease**
  The following criteria must be met:
  1. Documentation of a diagnosis of Kawasaki disease
  AND
  2. Treatment with IVIG is begun within 10 days of the onset of fever **OR**
  3. Patient has a delayed diagnosis (i.e., later than day 10 of fever) with ongoing systemic inflammation as manifested by elevation of ESR or CRP (CRP>3.0mg/dL) together with either persistent fever without other explanation or coronary artery aneurysms.

- **Pediatric HIV infection – Bacterial infection prevention**
  The following criteria must be met:
  1. Indicated in HIV positive children with humoral immunodeficiency **AND**
  2. Entry CD4+ lymphocyte count of 200/mm^3 or greater **AND**
  3. Hypogammaglobulinemia AND one or more of the following:
  4. Recurrent serious bacterial infections **OR**
  5. Failure to form antibodies to common antigens **OR**
  6. There is a high risk for measles **OR**
  7. There is a documented bronchiectasis that has not adequately responded to antimicrobial and pulmonary therapy.

- **Bone Marrow Transplantation (for lines of business not covered by the transplant vendor only)**
  The following criteria must be met:
  1. The transplant recipient is within the first 100 days after transplant from a matched unrelated donor **OR**
  2. Documentation of treatment of Graft vs. Host Disease in a transplant recipient receiving allogenic matched bone marrow transplant with chronic repeated infections or hypogammaglobulinemia (IgG levels less than 400 mg/dL) **OR**
  3. Documentation of autologous transplant with hypogammaglobulinemia (IgG level less than 400 mg/dL) or repeated infections.

- **Myasthenia Gravis (Acute use)**
  The following criteria must be met:
  1. Must be prescribed by a neurologist **AND**
  Medical documentation of one of the following indications:
  2. Diagnosis of acute myasthenic crisis with decompensation **OR**
  3. Use during postoperative period following a thymectomy for acute exacerbations **OR**
  4. Use prior to planned thymectomy **OR**
  5. For short term bridge therapy (one-course of treatment) in patients with acute worsening symptoms with plans to start other immunosuppressive treatments or corticosteroids.

IVIG for any of the above acute indications will be approved for one course of treatment. One course of treatment will be limited to 5 days of IVIG therapy.

- **Refractory Chronic Debilitating Myasthenia Gravis**
  1. Medical record documentation of refractory Chronic Debilitating Myasthenia Gravis **AND**
  2. Prescribed by or in consultation with a neuromuscular specialist **AND**
  3. Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one corticosteroid **AND**
  4. Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one cholinesterase inhibitor **AND**
  5. Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one non-steroidal immunosuppressive therapy

- **Dermatomyositis and Polymyositis**
  All of the following criteria must be met:
  1. Diagnosis of dermatomyositis or polymyositis confirmed by biopsy **AND**
  2. Documented evidence of active disease **AND**
  3. Must be prescribed by a neurologist **AND**
  4. Documented evidence that the condition is refractory to both of the following therapies
     A) First line therapy: corticosteroids (at least 4 months of therapy)
     B) Second line therapy: at least two immunosuppresants (e.g. cyclosporine, azathioprine, methotrexate, cyclophosphamide)

- **Guillain-Barre Syndrome/Ascending Paralysis**
  The following criteria must be met:
  1. A diagnosis of either acute or chronic Guillain-Barre syndrome **AND**
  2. Must be prescribed by a neurologist **AND**
  3. IVIG will be initiated within 2 weeks but no longer than 4 weeks of neuropathic symptom onset if acute onset **AND**
  4. No plan for combining IVIG with plasma exchange or sequential plasma exchange and IVIG.

- **Chronic Inflammatory Demyelinating Polyneuropathy**
  All of the following criteria must be met:
  1. Must be prescribed by a neurologist **AND**
  2. Documented evidence of focal or symmetric neurologic deficits that are slowly progressive or relapsing over 2 months or longer **AND**
  3. Physician provided documentation of EMG abnormalities consistent with the diagnosis of Chronic Inflammatory Demyelinating Polyneuropathy with the presence of at least ONE of the following:
     a. Motor distal latency prolongation $\geq$ 50% above upper limit of normal (ULN) in two nerves (excluding median neuropathy at the wrist from carpal tunnel syndrome) **OR**
     b. Reduction of motor conduction velocity $\geq$ 30% below lower limit of normal (LLN) in two nerves **OR**
     c. Prolongation of F-wave latency $\geq$ 20% above ULN in two nerves (> 50% if amplitude of distal negative peak CMAP <80% of LLN values) **OR**
     d. Absence of F-waves in two nerves if these nerves have distal negative peak CMAP amplitudes $\geq$ 20% of LLN + $\geq$ 1 other demyelinating parameter in $\geq$ 1 other nerve **OR**
     e. Partial motor conduction block: $\geq$ 30% amplitude reduction of the proximal negative peak CMAP relative to distal, if distal negative peak CMAP $\geq$ 20% of LLN, in two nerves, or in one nerve + $\geq$1 other demyelinating parameter in $\geq$ 1 other nerve **OR**
     f. Abnormal temporal dispersion (>30% duration increase between the proximal and distal negative peak CMAP) in $\geq$ 2 nerves **OR**
     g. Distal CMAP duration (interval between onset of the first negative peak and return to baseline of the last negative peak) increase in $\geq$ 1 nerve (median $\geq$ 6.6 ms, ulnar $\geq$ 6.7 ms, peroneal $\geq$ 7.6 ms, tibial $\geq$ 8.8 ms) + $\geq$ 1 other demyelinating parameter in $\geq$ 1 other nerve

Improvement should be apparent after 3 months of treatment; otherwise, requests for further treatment will require Medical Director review.

- **Fetal or Neonatal Alloimmune Thrombocytopenia (FNAIT)**
  The following criteria must be met:
  1. History of previous fetus or newborn with serologically confirmed Fetal or Neonatal Alloimmune Thrombocytopenia (FNAIT) with thrombocytopenia **OR**
  2. History of previous fetus or newborn with serologically confirmed Fetal or Neonatal Alloimmune Thrombocytopenia (FNAIT) with intracranial hemorrhage **OR**
  3. History of previous fetus or newborn with thrombocytopenia or intracranial hemorrhage of unknown etiology **AND** documentation a complete diagnostic workup was performed*

*Note, a complete diagnostic workup, per ACOG guidelines may include:
- Maternal anti-HPA antibody screening and cross matching with paternal platelets at 12, 24 and 32 weeks OR
- Paternal incompatibility for human platelet antigen OR
- A single antibody screening study including the crossmatching of paternal and maternal platelets at 30 weeks gestation

- **Multifocal Motor Neuropathy**
  The following criteria must be met:
  1. Must be prescribed by a neurologist **AND**
  2. Medical documentation of progressive symptoms for a minimum of 1 month **AND**
  3. Asymmetric limb weakness in at least two nerves **AND**
  4. No objective sensory abnormalities except for minor vibration sense abnormalities in the lower limb **AND**
  5. Documentation of a diagnosis of multifocal motor neuropathy with conduction block as shown on electrophysiologic study as evidenced by:
     - Definite Conduction block on a single nerve
       OR
     - Probable Conduction block in at least two nerves

OR

- Probable Conduction block in at least one nerve AND at least two (2) of the following:
    i. Elevated IgM anti-ganglioside GM1 antibodies
    ii. Increased CSF protein
    iii. increased T2-signal intensity on MRI of brachial plexus with diffuse nerve swelling
    iv. Objective clinical improvement following IVIG treatment

- **CMV Interstitial Pneumonia in Allogenic Bone Marrow Transplant or HSCT patients** (Ib/A)
  The following criteria must be met:
  1. Medical record documentation of CMV pneumonia
  2. Medical record documentation that IVIG is being used in combination with or patient has a contraindication to ganciclovir

- **Toxic shock syndrome** (III/C)
  The following criteria must be met:
  1. Medical record documentation of severe disease and failure on, intolerance to, or contraindication to conventional therapy, which may include, but is not limited to surgical debridement, fluid replacement, vasopressors or antibiotic therapy **AND**
  2. Caused by staphylococcal organisms

  OR

  1. Medical record documentation of Streptococcal Toxic Shock Syndrome (TSS)

- **Graves' Ophthalmopathy** (Ib/A)
  The following criteria must be met:
  1. Medical record documentation of failure on, contraindication to, or intolerance to conventional treatment (corticosteroids)
  2. Prescription must be written by an ophthalmologist

- **Autoimmune Mucocutaneous Blistering Diseases (pemphigus, pemphigoid, pemphigus vulgaris, pemphigus foliaceus, Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis** (III/C)
  The following criteria must be met:
  1. Diagnosis must be substantiated by biopsy **AND**
  2. Failure or contraindication to two or more conventional therapies (corticosteroids, azathioprine, cyclophosphamide, etc.)
     OR
  3. Have rapidly progressive disease in which a clinical response could not be quickly achieved utilizing conventional therapy. IVIG would be given in conjunction with conventional therapy and only until such time as conventional therapy could take effect

Note: IVIG for the treatment of autoimmune mucocutaneous blistering disease must be used only for short-term therapy and not as maintenance therapy.

- **Solid Organ Transplant**
  The following criteria must be met:
  Prevention of acute humoral rejection
    - Medical record documentation that patient is at high risk for antibody-mediated rejection, including highly sensitized patients or receiving ABO incompatible organ

  OR
  Treatment of acute humoral rejection
    - Medical record documentation of antibody-mediated rejection

- **Rasmussen's Encephalitis** (IIb/B)
  The following criteria must be met:
  1. Medical record documentation that short-term amelioration of encephalitis is needed prior to definitive surgical therapy
  2. Medical record documentation of intractable focal motor seizures and progressive neurologic deterioration

- **Stiff-Person Syndrome** (Ib/A)
  The following criteria must be met:
  1. Prescription written by a neurologist

2. Medical record documentation of failure on, intolerance to, or contraindication to all standard therapies (muscle relaxants, benzodiazepines, and gabapentin-related medications)

- **Eaton-Lambert myasthenic syndrome** **(Ib/A)**
  All of the following criteria must be met:
  1. Prescription written by a neurologist
  2. Medical record documentation of failure on, contraindication to, or intolerance to other treatments including corticosteroids or other immunosuppressants, cholinesterase inhibitors, and 3,4-diaminopyridine.

- **Multiple Sclerosis (relapsing/remitting type)**
  All of the following criteria must be met:
  1. Must be prescribed by a neurologist **AND**
  2. Medical record documentation of RRMS **AND**
  3. Medical record documentation of current MS exacerbation **AND**
  4. Medical record documentation of therapeutic failure on, contraindication to, or intolerance to an appropriate trial of high dose corticosteroids

Improvement should be apparent after 2 courses of monthly treatment, otherwise, requests for further treatment will require Medical Director review of supporting documentation of expected outcome.

Note: IVIG is considered investigational for primary or progressive multiple sclerosis and will not be covered.

- **Warm Antibody Autoimmune hemolytic anemia** **(III/D)**
  The following criteria must be met:
  1. Refractory to or contraindicated to corticosteroids and immunosuppressive agents
  2. Refractory to splenectomy

- **Parvovirus B19 Infection**
  All of the following criteria must be met
  1. Prescribed by or in consultation with an infectious disease specialist, immunologist, hematologist, or transplant specialist
  2. Medical record documentation of chronic immunodeficient condition (HIV, solid organ transplant, etc.)
  3. Medical record documentation of chronic parvovirus B19 infection
  4. Medical record documentation of severe anemia as defined by hemoglobin < 8 g/dL

- **Catastrophic Antiphospholipid Syndrome (CAPS)** **(III/C)**
  All of the following criteria must be met:
  1. Documentation of patient with antiphospholipid syndrome (APS) with multiorgan failure (evidence of involvement of <u>two</u> or more organs, systems, and/or tissues) **AND**
  2. Development of manifestations simultaneously or in less than one week **AND**
  3. Confirmation by histopathology of small vessel occlusion in at least one organ or tissue **AND**
  4. Laboratory confirmation of the presence of antiphospholipid antibodies (lupus anticoagulant, anticardiolipin antibodies, and/or anti-beta2-glycoprotein I antibodies) **AND**
  5. Medical record documentation Intravenous Immunoglobulin (IVIG) will be used in combination with conventional therapies (eg. anticoagulation and corticosteroids).

  OR
  1. Documentation of patient with antiphospholipid syndrome (APS) with multiorgan failure (evidence of involvement of <u>three</u> or more organs, systems, and/or tissues **AND**
  2. Development of manifestations simultaneously or in less than one week **AND**
  3. Laboratory confirmation of the presence of antiphospholipid antibodies (lupus anticoagulant, anticardiolipin antibodies, and/or anti-beta2-glycoprotein I antibodies) **AND**
  4. Medical record documentation Intravenous Immunoglobulin (IVIG) will be used in combination with conventional therapies (eg. anticoagulation and corticosteroids).

  OR
  1. Documentation of patient with antiphospholipid syndrome (APS) with multiorgan failure (evidence of involvement of <u>three</u> or more organs, systems, and/or tissues **AND**
  2. Confirmation by histopathology of small vessel occlusion in at least one organ or tissue **AND**

3. Laboratory confirmation of the presence of antiphospholipid antibodies (lupus anticoagulant, anticardiolipin antibodies, and/or anti-beta2-glycoprotein I antibodies) **AND**
4. Development of a third event in more than a week but less than a month, despite anticoagulation **AND**
5. Medical record documentation Intravenous Immunoglobulin (IVIG) will be used in combination with conventional therapies (eg. anticoagulation and corticosteroids).

AND FOR ALL INDICATIONS:

- **For Asceniv (immune globulin intravenous, human – slra) requests:**
  The following criteria must be met
  1. Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least three (3) immune globulin products.

AUTHORIZATION DURATION: Each treatment period will be defined as 6 months or less, unless otherwise stated (e.g. Chronic Inflammatory Demyelinating Polyneuropathy, Multiple Sclerosis, and Multifocal Motor Neuropathy). Re-review will occur every 6 months or less, dependent on the indication. Documentation of clinical response to therapy is required after initiation of therapy. If initial benefit is seen and continued therapy is deemed necessary, documentation of objective monitoring must be seen. Clinical improvement is superior to laboratory monitoring. IVIG will no longer be covered if there is a medical record documentation of disease progression.

LIMITATIONS: When approved, IVIG will be administered in a setting determined by the Plan, in consultation with the requesting physician to be the most clinically appropriate and/or medically necessary.

Initial Dosing: Dosing should be calculated using adjusted body weight (ABW) if one or more of the following criteria are met:

- Patient's body mass index (BMI) is 30 kg/m^2 or more
- Patient's actual body weight is 20% higher than his or her ideal body weight (IBW)

Dosing formulas:

- BMI = weight in kg / height in $meters^2$
- IBW (kg) for males = 50 + [2.3 (height in inches – 60)]
- IBW (kg) for females = 45.5 + [2.3 * (height in inches – 60)]
- ABW = IBW + 0.5 (actual body weight – IBW)

Geisinger Health Plan considers some conditions other than those listed under Indications to be **Experimental, Investigational or Unproven** and **NOT Medically Necessary**. These conditions include:

- Alzheimer's disease
- amyotrophic lateral sclerosis
- atopic dermatitis
- autism
- chronic fatigue syndrome
- chronic mucocutaneous candidiasis (CMCC)
- complex regional pain syndrome (CRPS)
- epilepsy
- inclusion body myositis
- Lyme disease
- neuromyelitis optica (NMO) (Devic's Disease)
- optic neuritis
- paraproteinemic demyelinating neuropathy (PDN)
- post-polio syndrome
- recurrent spontaneous miscarriage
- rheumatic fever
- secondary progressive multiple sclerosis (SPMS)

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 11/01

Revised: 8/02 (add indication, coding); 1/1/03 Coding; 8/05; 5/07; 11/09(coding); 12/12, 2/13 (coding); 11/18/14 (add indications, authorization duration, add new criteria, dosing criteria, coding), 03/24/15 (add Hygvia, requirements and auth duration), 3/21/17 (Cuvitru added), 3/20/18 (MG updated), 7/17/18 (chronic MG), 3/19/19 (added Panzyga), 9/17/19 (Cutaquig), 12/13/19 (per DHS), 12/24/21 (full policy review and edits from Dec 2021 P&T), 5/17/22 (CAPS criteria edit, added Medicaid PARP statement), 12/21/22 (LOB carve out), 12/20/23 (Medicaid business segment), 1/26/24 (Hyqvia indication del in product list), 10/18/24 (add Alyglo [from Sep 2024 P&T], update EMG for CIDP)

Reviewed: 11/18/14, 3/31/16, 9/30/20, 9/24/21