



SPECIALTY INFUSION

# **Pemphigus & Pemphigoid**

## **IVIg, Insurance Benefits and Kroger Specialty Infusion**

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*Viki Figge*

*VP of Sales*

# IVIG

IVIG is an effective therapy in the treatment of patients with Pemphigus.



# Treatment with IVIG

- There is a general agreement that IVIG is indicated for the control of Pemphigus unresponsive to conventional therapy, or when a serious complication to standard therapy occurs.
- Other suggested indications include inability to withdraw steroids without a flare in disease activity, absolute or relative contraindications to the use of systemic steroids, and progressive disease despite appropriate but safe conventional therapy.

# What Is

# IVIG

# ?



**Intravenous Immunoglobulin (IVIG) is a solution of highly purified immunoglobulin G, derived from large pools of human plasma that contain antibodies against a broad spectrum of bacterial and viral agents.**

# IVIG

- The mechanism of action of IVIG is very similar to that of Plasmapheresis. Both procedures rapidly remove circulating Pemphigus antibodies from the circulation and do so at about equal rates. However, *IVIG has the major **advantages** over Plasmapheresis* that the Pemphigus antibodies are removed selectively, whereas Plasmapheresis as usually performed removes all circulating immunoglobulins, the good with the bad.
- Furthermore, IVIG appears to be safer as it does not damage red blood cells and is less damaging to venous access.

# IVIIG in the US Market

- Gammagard Liquid-Baxalta/Shire
- Gammagard S/D-Baxalta/Shire
- Gamunex-C-Grifols
- Privigen-CSL
- Gammaked-Kedrion
- Gammaplex-BPL
- Octagam-Octapharma
- Flebogamma-Grifols
- Carimune-CSL
- Bivigam-Biotest/Kedrion
- Hizentra-CSL
- HyQvia-Baxalta/Shire

# Brand Selection

- Not all Ig products are the same.
- It is important to have access to all products to make appropriate clinical decisions that are in the best interest of patients.
- Many factors play into product selection such as age, comorbidities, allergies, hypersensitivity and contraindications.
- Kroger Specialty Infusion works closely with our prescribing physicians to obtain a complete medical history on our patients before selecting an Ig product.
- Kroger Specialty Infusion works with all manufactures to assure access of all products on the market.

# Brand Selection

Appropriate brand selection of Ig products can reduce the number of adverse events and lead to better patient outcomes.

<b>Patient Characteristics</b>	<b>Product Characteristics</b>
Age of patient	Sugars/stabilizers
Comorbidities	Sodium
Medical history	IgA content
History of previous Ig use	Osmolality
Allergies	Formulation Concentration

# IVIg and Insurance Plans

An important element in the decision of treating Pemphigus with IVIG are the policies of Medicare or of the insurance plan that will pay for the treatment. The indications vary with each plan, and Medicare's indications vary from region to region in the US.

# Insurance Options for Home Infusion Services

- Home infusion services are typically covered by the following insurance carriers:
  - » Medicare
  - » Champus/Tricare
  - » Medicaid/Medi-Cal
  - » Commercial Payers
    - PPO's(Preferred Provider Organizations)
    - HMO's(Health Maintenance Organizations)
    - POS(Point of Service)
    - EPO(Exclusive Provider Organization)
  - » Private Insurance Carriers

# Commercial Plan Types

**HMO(Health Maintenance Organization)** – If in an HMO, patient must use network providers, doctors, hospitals, and other health care providers that participate in the plan. The only exception is emergency care. An HMO requires the selection of a PCP(Primary Care Physician) to manage the patient's care with other in-network providers. All providers must be in-network and prior authorization is typically required from the primary care physician before services can be rendered.

**PPO(Preferred Provider Organization)** - With a PPO, the patient receives more comprehensive benefits by using in-network providers, doctors, hospitals, and other health care providers that participate in the plan. The patient often has the option of using non-network providers, but with a lower level of benefits and higher out-of-pocket costs. Because PPOs usually have broader networks, they are generally more expensive – have higher premiums –than HMOs and EPOs. With a PPO, the patient does not need to select a Primary Care Physician.

# Commercial Plan Types - continued

**EPO(Exclusive Provider Organization)** – A more restrictive type of preferred provider organization plan under which plan members must use providers from the specified network of providers, physicians, and hospitals to receive coverage; there is no coverage for care received from a non-network provider except in an emergency situation.

**POS(Point of Service)** – A HMO/PPO hybrid plan; sometimes referred to as an “open-ended” HMO. POS plans resemble HMOs for in-network services. Typically, POS plans have a network that functions like a HMO – the patient picks a primary care doctor, who manages and coordinates their care within the network. POS plans also allow you to use a provider who is not in the network. However, if you choose to go out-of-network for care, out-of-pocket costs will be much higher.

# Medicare Plan Types and Coverage Criteria

## Medicare Part A

- Part A – Covers Inpatient Hospital stays, Skilled Nursing Facility (SNF), and Hospice care but **does not** offer benefits for Home Infusion services
- We cannot provide medication or services to a patient when they are in the hospital or in a SNF; the hospital or SNF is required to provide all medications and services required by the patient

# Medicare Plan Types and Coverage Criteria

## Medicare Part B

### Medicare B covers:

- Services like lab tests, surgeries and Dr. visits
- Supplies like wheelchairs and walkers considered medically necessary to treat a disease or condition

### Medicare B coverage is based on 3 main factors:

- Federal and state law
- National coverage decisions made by Medicare about whether something is covered
- Local coverage decisions made by companies in each state that process claims for

Medicare. These companies decide whether something is medically necessary and should be covered in their area.

# Medicare Plan Types and Coverage Criteria

## Medicare Part B

### **IVIG Reimbursement:**

- Average Selling Price (ASP) + 6%, drug only
- Depending on the product prescribed, drug reimbursement can be negative or barely break-even
- Patients must enroll in the Medicare Demonstration project (\$336.05 per infusion) – this is the incremental reimbursement designated to cover nursing and supplies

### **SCIG Reimbursement:**

- Average Wholesale Price (AWP) – 5%, drug only
- All products have a favorable drug margin

### **Medicare B Reimbursement:**

- Pays at 80%/20% (similar to a physician office visit) after deductible of \$166 is met
- Most patients have a secondary plan that picks up the 20% cost

# Medicare Plan Types and Coverage Criteria

## Medicare Part C

- A Medicare Advantage Plan is a type of Medicare health plan offered by a private insurance company that contracts with Medicare and provides Part A and Part B benefits. Medicare Advantage Plans are Managed Care Plans where the patient signs over their Medicare benefits to enroll with this particular type of plan. If enrolled in a Medicare Advantage Plan, Medicare services are covered through the plan and aren't paid for under original Medicare. Many Medicare Advantage Plans offer prescription drug coverage. A Medicare Advantage plan that offers Medicare prescription drug coverage is called an MAPD(Medicare Advantage Prescription Drug) Plan.
  - » Providers need to be in network to participate with most Medicare Advantage Plans. These are managed care plans and **do not** normally offer out-of-network benefits.

# Medicare Plan Types and Coverage Criteria

## Medicare Part D

- Covers Home Infusion Drugs for a diagnosis that is not covered by Medicare Part B. These are primarily neurological diagnoses. Coverage is for drug only; no additional supplies or services are reimbursed
- This coverage is available to Medicare beneficiaries for an additional charge. The coverage is offered by multiple insurance companies approved by Medicare.
- Part D will not pay for drugs that are covered under Part A or Part B. There is no combining of Part A or B and D benefits.
- The different Part D plans offer different levels of reimbursement for different products. Some may have a formulary and require use of a particular Ig brand.
- Kroger Specialty Infusion can service almost all patients with a qualifying diagnosis who have a Part D plan. A carve-out is very rare but that could change in the future.

# Most Common Medicare D Diagnosis for IVIG

- Acute Infective Polyneuritis (Guillain-Barre Syndrome)
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
- Dermatomyositis
- Inflammatory Polyneuropathy, Unspecified (MMN)
- Multiple Sclerosis (MS)
- Myasthenia Gravis with (Acute) Exacerbation
- Myasthenia Gravis without (Acute) Exacerbation
- **Pemphigus (Pemphigus Foliaceus, Pemphigus Vulgaris)**
- Polymyositis
- Stiff-Person Syndrome

# Part D Benefit Structure - 2016

- Initial Deductible is \$360 – patient pays 100%
- Initial Coverage Limit Period - \$2,950 – patient pays 25%
- Coverage Gap (Donut Hole) – Once cost exceeds \$3,310 (\$360 + \$2,950), patient pays 45% for covered brand name drugs
- Out-of-Pocket Threshold is \$4,850
- Catastrophic Coverage – Once cost exceeds \$4,850, patient pays 5% of the drug cost. Part D plan pays 95%

# What to Expect from Kroger Specialty Infusion

Kroger Specialty Infusion was founded on the principle of providing superior service and care to patients requiring Ig Therapy as well as critical Home Infusion Therapy. Because of our superior clinical service, expertise, nursing and patient advocacy, we rapidly gained attention to become one of the leading specialty infusion companies in the nation.

Our focused approach to disease management along with our expertise in complex illnesses allows us to offer a wide range of therapeutic medications and treatments. Kroger Specialty Infusion is also a leading provider of plasma therapies for patients diagnosed with autoimmune and primary immune deficiencies.

# Three-Pronged Approach (designed to mitigate potential barriers and help our patients start and continue successful treatment)

- **Educational**-Designed to provide patient information on both the nature of their condition as well as the benefits of treatment.
- **Behavioral**-In order for patients to successfully maintain adherence, their treatment must become part of their routine.
- **Social**-In order for patients to successfully maintain adherence, their treatment must become part of their routine.

# What to Expect from Kroger Specialty Infusion:

- **Patient Access Coordinators** begin the education process by initiating a phone call to you our patient welcoming you to Kroger Specialty Infusion.
- PACS will provide you with information about manufacturer sponsored assistance programs and address questions you may have regarding the insurance component of their therapy.
- PACS will contact your insurance carrier and begin the “Auth Process.”

# Auth Process/Pharmacists

- Our pharmacy has a team of specialized individuals with both an extensive knowledge of the prior authorization process, as well as the important clinical elements of Ig therapy. They are directly involved in the PA process.
- The pharmacists review the clinical notes, laboratory results and diagnostic studies
- They will converse with the prescriber and help with Peer to Peers.
- This team of Intake Coordinators work closely with our referring physicians to obtain all of the necessary clinical documentation for prior authorization submission.

# Clinical documentation commonly required when requesting prior authorization

## **Autoimmune Mucocutaneous Blistering Diseases:**

- Pemphigus Vulgaris
- Pemphigus Foliaceus
- Bullous Pemphigoid
- Pemphigoid (a.k.a. Cicatrice Pemphigoid)
- Epidermolysis Bullosa Aquisita

## **Indications:**

1. The diagnosis has been proved by lesional tissue biopsy and confirmed by pathology report (serology); and Otolaryngologist, Dentist, Dermatologist History and exam, a blister biopsy, direct immunofluorescence skin biopsy, antibody titer test; and
2. The condition is rapidly progressing, extensive or debilitating; and
3. Corticosteroids (ex. Prednisone), immuno-suppressive agents (ex. Cellcept, Methotrexate) have failed or the patient has experienced significant complications from standard treatment , such as diabetes or steroid-induced osteoporosis.

# Clinical documentation commonly required when requesting prior authorization

## **Dermatomyositis**

**Clinicals needed:** Magnetic resonance imaging (MRI), Electromyography (EMG), Muscle biopsy, blood analysis, Skin biopsy, clinicals showing all previous treatments tried without success.

## **Polymyositis (“inflammation of many muscles”)**

**Clinicals needed:** Magnetic resonance imaging (MRI), Electromyography (EMG), Muscle biopsy, blood tests, clinicals showing all previous treatments tried without success.

# Advocacy

- Our **Patient Advocacy Support** team becomes involved through initial outreach to new patients. There is probably nothing more impactful for a patient than being able to share their experience with another individual who has faced the same challenges.
- Our advocates listen, share and educate patients on their disease state and the therapy being ordered. As appropriate they will email, fax or mail information to them and will direct them to manufacturer websites for more information. This team is available to patients prior to the start of care and throughout the duration of their therapy.

# Nursing

- Once a case is ready for staffing, every patient will receive a call from our Nursing Department.
- Our nurses describe the type of treatment, giving education on the medication, side effects, appropriate storage, expectations of medication therapy and patient preparation prior to therapy.
- Prior to the end of the call, patients are given an 800 number with 24 hour access to a pharmacist.

# Pharmacists

- Our Pharmacists are also responsible for communicating with all new patients.
- This is via telephone communication where we discuss treatment goals and potential side effects of the prescribed medication.
- We also review current medications with our patients and help tailor a specific plan of care for them.
- Our pharmacists normally spend between 30-45 minutes with every new patient.

# On Going Therapy

- Finally a patient receives live support through our nursing education visits.
- Our nurses are experts in the administration of IVIG and SCIG training. In addition to providing hands-on education in the home, our nurses communicate directly with our pharmacy staff if any follow-up questions need to be addressed.
- The nurse reinforces expected outcomes of therapy and counsels the patient on whom to contact should any adverse reaction to the medication occur.

# Patient Financial Support Programs

- **Manufacturer Co-Pay Assistance Programs** – Only commercially insured patients are eligible; per fill or annual limitations vary by program; financial qualifications vary by program
  - ❑ CSL – Hizentra – PID and SCIG only
  - ❑ Grifols – Gamunex-C – CIDP/PID – IVIG and SCIG
  - ❑ Baxalta – Gammagard – PID and SCIG only; ages 2 – 15 years unless patient already enrolled
  - ❑ Baxalta – HyQvia – PID and SCIG only
  - ❑ BPL – Gammaplex – All diagnoses; IVIG
- **ModernHEALTH Care Support Program** – Option for all patients regardless of payer

# Kroger Care Support Program

- This is **NOT** a sales tool and should not be used as such in the field
- Program is meant to provide financial support in the form of relief for payment of deductibles, co-pays or other out-of-pocket expenses
- Patient must express a financial hardship before we can discuss the program with them
- ModernHEALTH program complies with Federally mandated criteria – the government sets the Federal Poverty Limit each year; the FPL varies by city and state
- Patient must fill out an application that provides household size and income; supporting documentation of income must be provided
- Patients qualify for 100% support if their income falls below 300% of the FPL; 75% if their income is between 300-399% of the FPL and 0% if their income is >400% of the FPL
- The patient is asked to submit a renewal application approximately once a year

# Our Mission Statement

It is our mission to be the preferred pharmacy service by optimizing outcomes and providing a high-touch, caring experience.

# Medi-Cal, CCS, and Out-of-State Medicaid

- Medi-Cal, California Children's Services (CCS), and out-of-state Medicaid are joint federal/state programs that help with medical costs for some people with limited income and resources. These programs vary from state to state.
- Most Medicaid programs provide coverage for care provided in the home setting. While many Medicaid programs cover care in the home setting, some do not provide separate reimbursement for drugs. Where separate payment for drugs is provided, payment is typically based on a percentage of AWP(Average Wholesale Price), WAC(Wholesale Acquisition Cost), ASP(Average Sale Price), or state-specific fee schedules. There are significant variations in Medicaid payments among states. Its important to check with each specific state Medicaid program to determine its policies.
- Many states are moving their Medicaid program to multiple Managed Medicaid providers
  - » Prior authorization is always required for these plans.

# Commercial/Private Insurance

- Examples: UHC, Aetna, Humana, BCBS, Cigna
- Most health plans provide a three component payment system for home infusion:
  1. **Drugs** – The majority of health plans pay for the drugs based on a discount off the Average Wholesale Price (AWP). A few health plans base their drug payments on a percentage of the Wholesale Acquisition Cost (WAC) or Average Selling Price (ASP).
  2. **Per Diem** – The majority of health plans pay a per diem to cover supplies, equipment, pharmacy services, and other non-nursing services, such as administrative and care coordination services.
  3. **Nursing** – The majority of health plans pay for nursing on a per visit basis, encompassing a set rate for the first two hours, and a set additional hourly rate for any hours over the first two hours of nursing care provided.

**\* Prior Authorization or Predetermination is required for all items listed above.**

# In-network benefits vs. out-of-network benefits

**In-Network** coverage is when the provider providing service participates fully with a particular health plan and has a contractual agreement with them. When going in-network, the patient's responsibility is to pay the deductible, co-pay, or coinsurance portions, and the rest is covered by the insurance carrier based on a pre-negotiated price with the provider. By going in-network the patient out-of-pocket expenses are typically lower.

**Out-Of-Network** coverage is when the provider providing service **does not** participate with a particular health plan and has no contractual agreement with them. If out-of-network the patient will have to pay a much larger portion of the bill as the health insurance plan will cover a much smaller fraction of the charges (e.g. 65% coverage vs. 80% coverage). The deductible and coinsurance portions are much higher with a much lower reimbursement percentage.

- » Please be aware that some health insurance plans may not even offer out-of-network benefits.
- » Out-of-network benefits often have caps, limitations, and carve-outs and can be priced very unfavorably (e.g. OON at 100% of Medicare B rates)

# Benefit Investigation (BI)

- First step after receipt of the referral
  - « Medicare A, B, D – Does the patient have active coverage? If Part D, what insurance carrier holds the plan?
  - « Secondary – Does a Medicare patient have an active secondary or supplemental plan?
  - « Medi-Cal, CCS, Out-of-State Medicaid – Does the patient have active coverage? Is Ig
  - « a covered benefit? Are we contracted? What is the rate of reimbursement?
  - « Commercial – Does the patient have active coverage? Type of plan/effective date?
    - Home infusion coverage? Ig covered through PBM or major medical?
    - Patient benefits (both in-network and out-of-network) - deductible, co-pay, co-insurance, pricing methodology & reimbursement rates, plan exclusions, claims mailing address, pre-authorization process, annual, lifetime, and daily maximums

# Commercial/Private Insurance

- **PAC performs a full benefit investigation to determine:**
  - « Is Kroger Specialty Infusion contracted with the payer?
  - « If not, is one of our other pharmacies contracted with the payer (IS, ITOT, TLCRx)?
  - « If contracted, can our sister pharmacy ship into the state where the patient resides?
  - « If not contracted, does the patient have out-of-network benefits?
- **PAC investigates drug reimbursement through the PBM (if applicable) or major medical**
  - « PBM may cover the drug or it may be a benefit exclusion
  - « Drug may be carved out to another pharmacy provider
  - « If a PBM benefit exclusion, PAC pursues coverage through major medical
  - « Drug may be covered through the pharmacy benefit with nursing and per diem covered through the major medical portion of the plan
  - « We may only be covered for the drug and may not the opportunity to be reimbursed for nursing or per diem (particularly if we are non-contracted)

# Prior Authorization

- Before Home Infusion therapy begins, plans must approve coverage. They generally ask physicians to report the diagnosis, prescribed drug, pertinent clinical documentation to support the diagnosis and drug prescribed, dosage, and expected duration of therapy. They may also request information about the patient's age, sex, and overall health status.
- Outside of Medicare Part B, 98% of all health plans that cover IVIG in the home require prior authorization because of its high cost and its use for multiple off-label indications (Spontaneous Abortion, Alzheimer's, etc.). Therefore, authorization is highly dependent on the patient having an insurance covered diagnosis.
- Though prior authorization is never a guarantee of payment, not obtaining it will be a certain denial of payment. Prior authorization represents authorization for payment as the coverage criteria for payment has already been established prior to service.
  - » Some plans conduct retrospective reviews after therapy has been started to determine if continued authorization will be provided. They do this based on clinical outcomes of the authorized treatment

# Prior Authorization

- Medicare B – Prior authorization is not required although Medicare reserves the right to audit after services are provided. A Kroger Specialty Infusion pharmacist reviews the clinical documentation to ensure it supports the diagnosis and use of Ig.
- Medicare D – Verify that the diagnosis is not a Medicare B covered diagnosis; Complete prior authorization form for the drug (brand, quantity, # fills); run a test claim to ensure the claim is payable to Kroger Specialty Infusion and not carved out to another pharmacy
- Medi-Cal, CCS, Out-of-State Medicaid – Complete prior authorization form for the drug (TAR, SAR, other); run a test claim to ensure the claim is payable to Kroger Specialty Infusion (if adjudicated online)
- Commercial -PBM – Form completed for the drug (brand, quantity, # fills); confirm the drug is not carved out to another pharmacy; confirm the fill is not transitional or under travel restrictions; run a test claim to receive a payable claim
- Commercial – Major Medical – If drug through PBM, submit required authorization for per diem and nursing; if no PBM, submit required authorization form to obtain approval for drug, per diem and nursing; depending on payer, authorization may be telephonic, online or faxed

# Clinical documentation commonly required when requesting prior authorization, listed by diagnosis

## **SCID(Severe Combined Immunodeficiency)**

**Clinicals needed:** Immunoglobulin Levels(IgG, IgM, IgA,IgE), CBC, clinicals showing all previous treatments tried without success, T-Cell, B-Cell, NK(Natural Killer) Cell Counts, pre and post pneumovax titers, Specific Genetic Testing.

## **Congenital Hypogammaglobulinemia**

**Clinicals needed:** Immunoglobulin Levels(IgG, IgM, IgA,IgE), CBC, Protein electrophoresis(blood or urine), T (thymus derived) lymphocyte count, white blood cell count, pre and post pneumovax titers, clinicals showing all previous treatments tried without success.

## **Hyper IgM Syndrome**

**Clinicals needed:** CBC & Immunoglobulin Levels(IgG, IgM, IgA,IgE), pre and post pneumovax titers, clinicals showing all previous treatments tried without success.

## **CVID(Common Variable Immunodeficiency)**

**Clinicals needed:** CBC & Immunoglobulin Levels(IgG, IgM, IgA,IgE), pre and post pneumovax titers, clinicals showing all previous treatments tried without success.

# Definitions of Health Insurance Terms

**Co-insurance** – A form of medical cost sharing in a health insurance plan that requires an insured person to pay a stated percentage of medical expenses after the deductible amount if any, was paid.

- Once any deductible amount and coinsurance are paid, the insurer is responsible for the rest of the reimbursement for covered benefits up to the insurance allowed amount: the individual could also be responsible for any charges in excess of what the insurer determines to be “usual, customary, and reasonable”.
- Coinsurance rates may differ if services are received from an approved provider (ie, a provider with whom the insurer has a contract or an agreement specifying payment levels and other contract requirements) or if received by providers not on the approved list.

**Co-payment** – A form of medical cost sharing in a health insurance plan that requires an insured person to pay a fixed dollar amount when a medical service is received. The insurer is responsible for the rest of the reimbursement.

- » There may be separate copayments for different services.
- » Some plans require that a deductible first be met for some specific services before a copayment applies

# Definitions of Health Insurance Terms - continued

**Usual, Customary, and Reasonable (UCR) charges** – Most Commercial plans operate based on usual, customary, and reasonable (UCR) charges. UCR charges mean that the charges is the provider's usual fee for a service that does not exceed the customary fee in the geographic area, and is reasonable based on the circumstances. In-network PPO plans often operate based on a negotiated (fixed) schedule of fees that recognize charges for covered services up to a negotiated fixed dollar amount.

**Predetermination** – A predetermination is a review by medical staff to determine if the service requested is appropriate. Predeterminations are done prior to services so that you will know in advance if services meet insurance plan coverage requirements.

**Prior Authorization** - Prior authorization is the process of obtaining insurance plan authorization prior to providing services. The purpose of the prior authorization function is to determine insurance plan member eligibility, benefit coverage, medical necessity, and appropriateness of services.

# Questions?

