Achieving Appropriate Access to High Quality Care for the Treatment of PRIMARY IMMUNODEFICIENCY

Jointly provided by:

PIM Postgraduate Institute for Medicine
Professional Excellence in Medical Education

IDF Immune Deficiency Foundation

Impact Education LLC

This program is supported by an independent educational grant from CSL Behring.

Welcome

James T. Kenney, RPh, MBA
President
JTKENNEY, LLC

Agenda

6:30 AM	Pre-Activity Learning Assessment and Opening Comments **James Kenney, RPh, MBA**
6:35 AM	*Clinical Overview of Primary Immunodeficiency: Signs, Symptoms, Screening, and Diagnostic Modalities* **Blachy J. Dávila Saldaña, MD**
7:00 AM	*Optimizing Treatment Selection and Dosing for PI based on Disease Type and Patient Characteristics* **James Kenney, RPh, MBA**
7:25 AM	*Medical and Pharmacy Management Strategies to Enhance PI Patient Outcomes in a Managed Care Setting* (case-based presentation) **James Kenney, RPh, MBA**
7:40 AM	Audience Q&A Session
7:55 AM	Key Takeaways and Closing Comments; Post-Activity Assessment and Evaluation
8:00 AM	Adjournment

Learning Objectives

- Describe the potential signs and symptoms of primary immunodeficiency (PI) in addition to predominant screening and diagnostic modalities
- Assess available therapeutic options for PI based on disease type and patient characteristics
- Characterize the adverse effect of excess cost-sharing on and prohibitive coverage criteria on patient access and adherence
- Implement medical and pharmacy benefit design strategies that improve access to therapy and manage costs with evidence-based clinical care for PI

Clinical Overview of Primary Immunodeficiency: Signs, Symptoms, Screening, and Diagnostic Modalities

Blachy J. Dávila Saldaña, MD
Attending Physician, Division of Blood and Marrow Transplantation
Director, Combined Immunodeficiency BMT Clinic
Fellowship Director, Bone Marrow Transplant and Cell Therapy
Children's National Hospital
Associate Professor of Pediatrics
George Washington University School of Medicine and Health Sciences

PI Disease Overview

- >400 individual rare and chronic disorders
- 250,000 individuals diagnosed in the United States
- Part of the body's immune system is missing or malfunctions
- Hereditary etiology
- Presents at birth or early childhood, but anyone can be affected, regardless of age

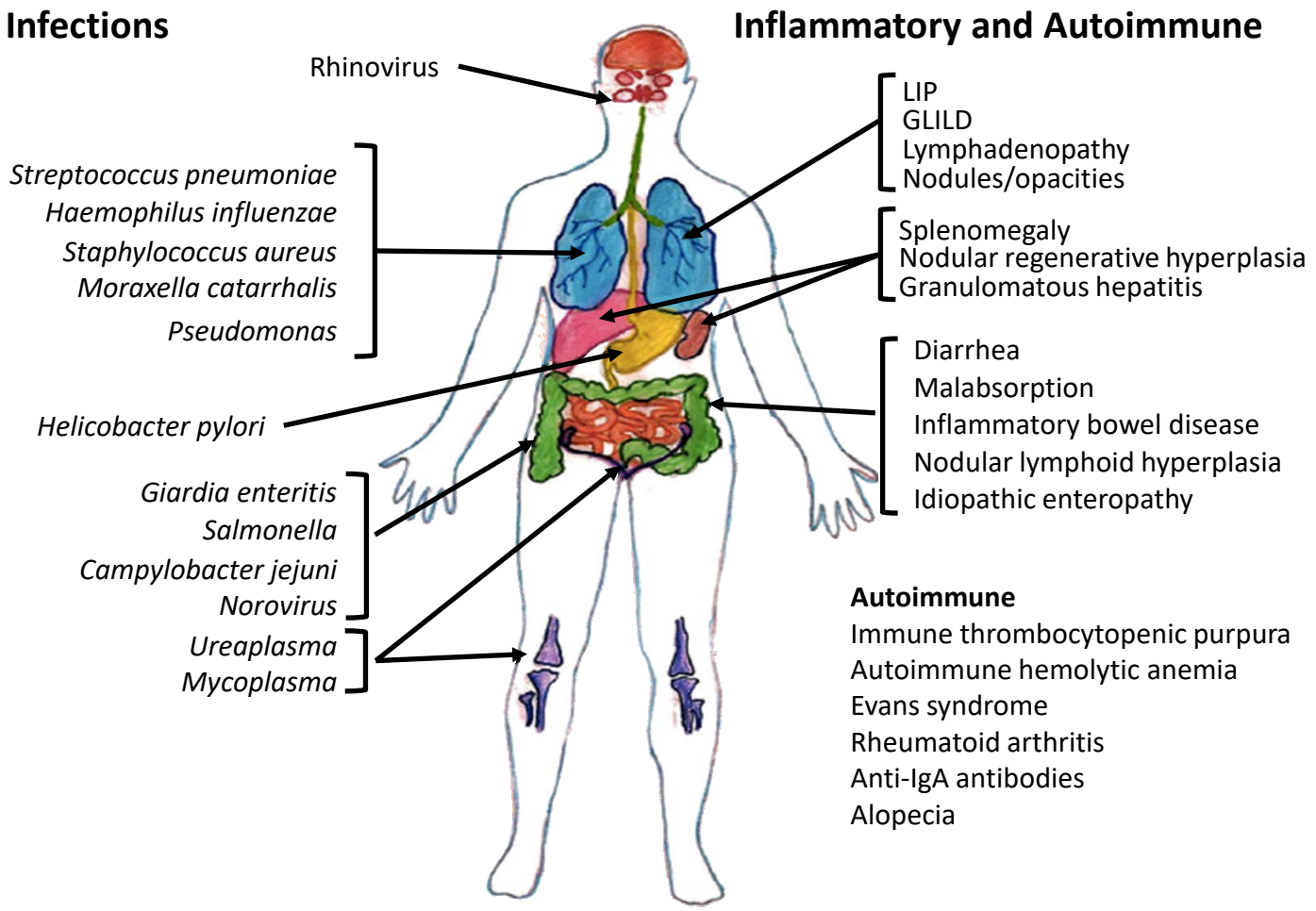
About the Immune Deficiency Foundation. Immune Deficiency Foundation. Accessed October 2022. https://primaryimmune.org/sites/default/files/IDF%20Fast%20Facts.pdf.

Clinical Features of Immunodeficiency

- Increased susceptibility to infection
- Predisposition for autoimmune or inflammatory diseases:
  - Inflammatory bowel disease
  - Autoimmune cytopenias
  - Type 1 diabetes
  - Juvenile rheumatoid arthritis
- Predisposition for lymphoreticular cancers
- Syndrome complex

Subbarayan A, et al. *Pediatrics.* 2011;127: 810-816.

Potential Clinical Sequelae Affect Multiple Organ Systems



McCusker C, et al. *Allergy Asthma Clin Immunol*. 2018;14(Suppl 2):61.

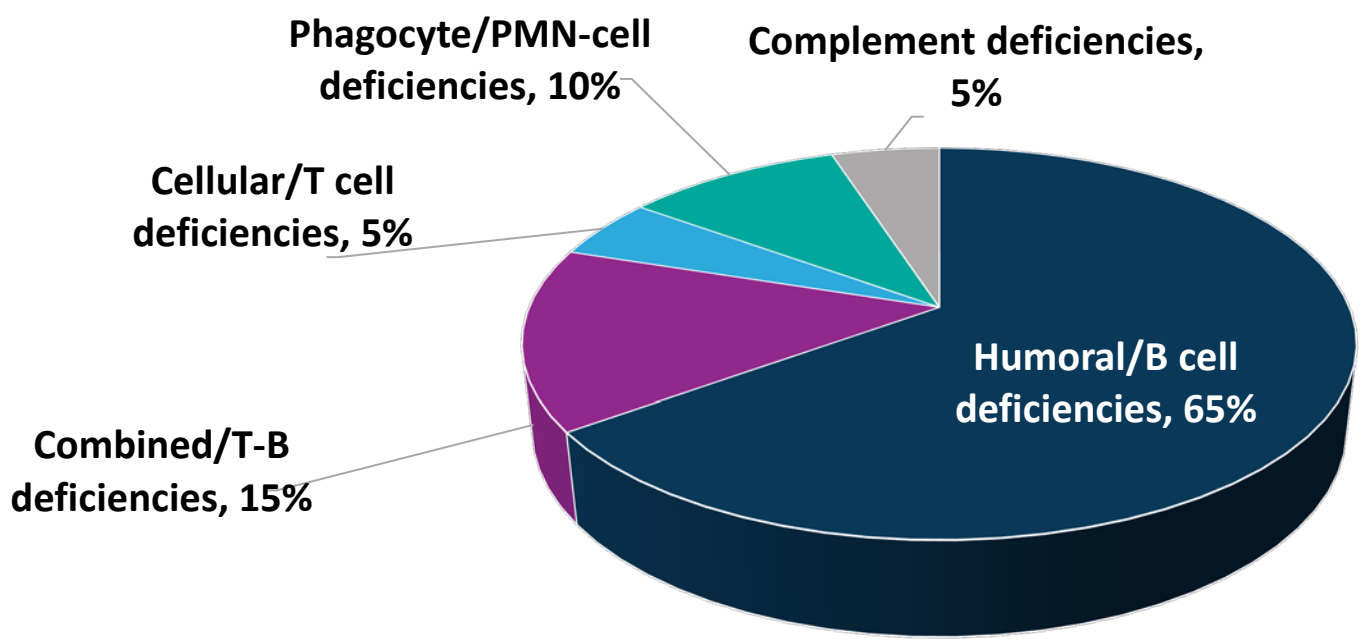
PI Epidemiology

Incidence

1/600 - 150,000

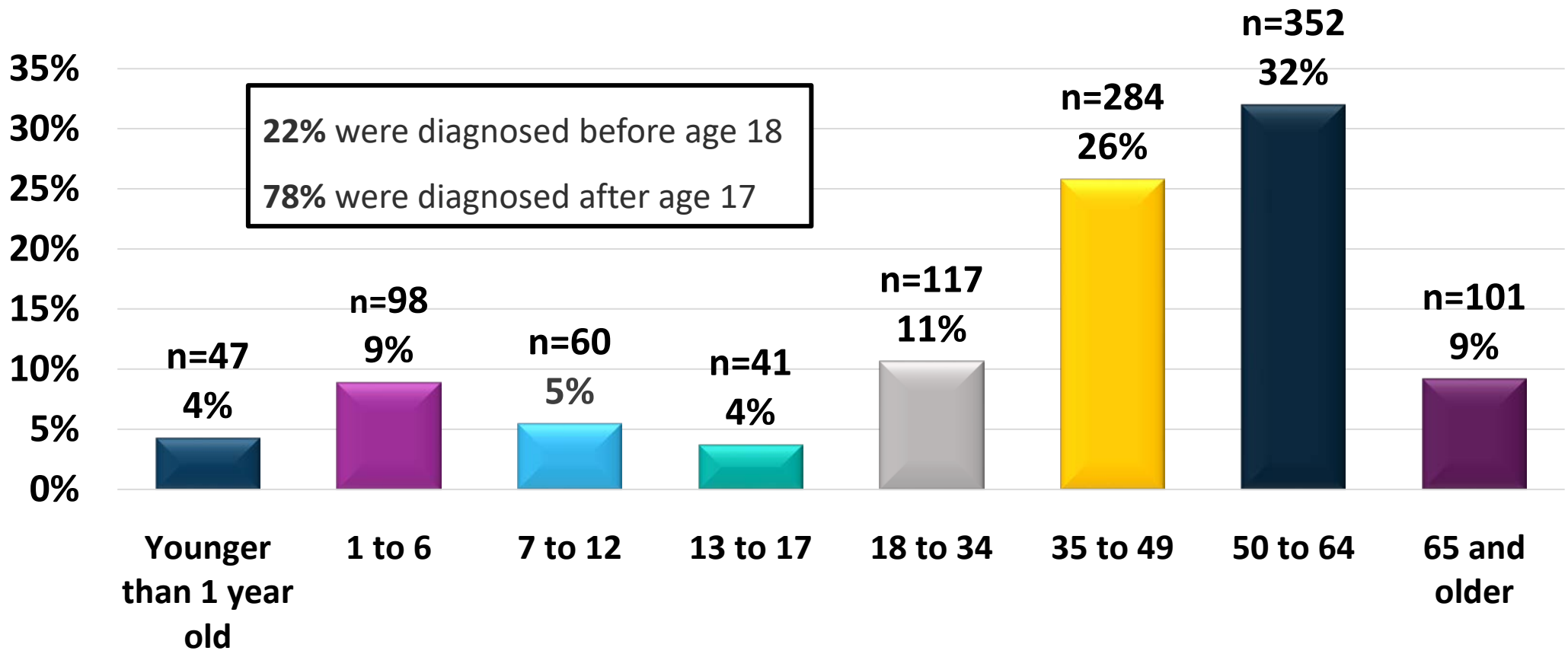
(2:1, ♂:♀)

Distribution



Abolhassani H, et al. *Expert Rev Clin Immunol*. 2020;16:717-732.

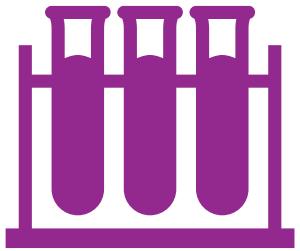
PI Presents in Childhood but is Often Diagnosed in Adulthood



Question: At what age (in years) was the patient first diagnosed with a PI? N=1,100
Base: All respondents

Source: IDF 2017 National Patient Survey

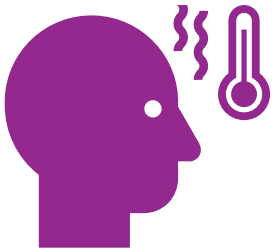
Key Components of PI Diagnosis



Immunological tests
(antibody levels, T cell function, vaccine response, etc.)

PI

Genetic testing

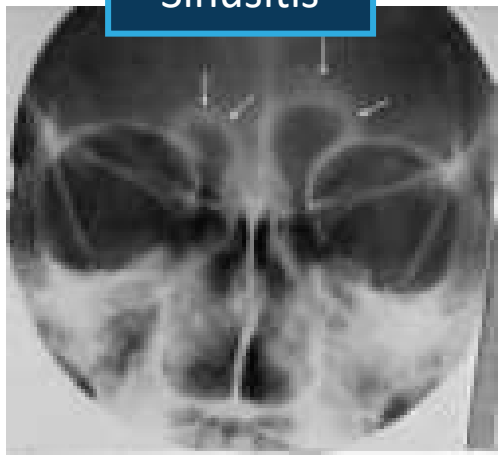


Clinical phenotype
(infections, autoimmunity, splenomegaly, inflammatory bowel disease, etc.)

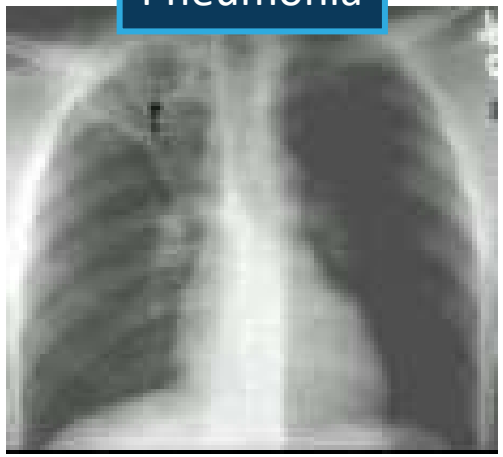
Clinical Phenotype: Infections

- Chronic/recurrent infections without other explanation
- Infection with organisms of low virulence
- Infection of unusual severity
- Any site of infection is possible, but different kinds of infection are characteristic of the specific immunodeficiency suspected

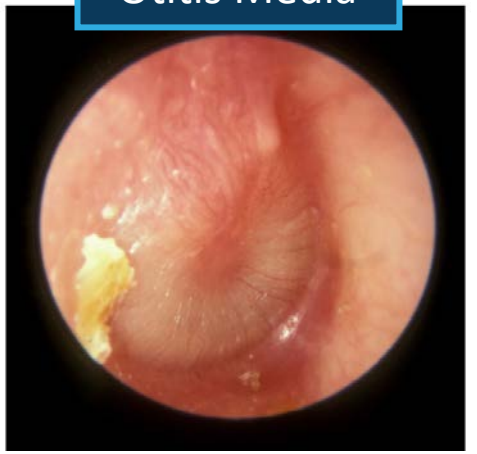
Sinusitis



Pneumonia



Otitis Media



Considerations Regarding Infections

- Type of infection
- Frequency
- Comorbidities
- Contributing factors
- Family history

Immunological Screening Tests

Complete Blood Count (CBC) +

Suspected Abnormality	Diagnostic tests
Antibody	Serum IgG, IgA, IgM Antibody response to vaccines
Cell-mediated immunity	Lymphocyte count T cell enumeration (CD4, CD8) HIV serology/PCR
Complement	Total hemolytic complement (CH_{50}) Alternative Pathway (AH_{50}) Mannan Binding Lectin
Phagocytes	Neutrophil count Dihydrorhodamine (DHR) test Nitroblue tetrazolium (NBT) dye test

Oliveira JB, et al. *J Allergy Clin Immunol*. 2010;125(2 Suppl 2):S297-305.

Normal Ranges of Immunoglobulins

Immunoglobulins (mg/dL)

Age	IgG	IgA	IgM
Newborn	636-1606	1-4	6-25
1-3 months	176-906	1-53	17-105
4-6 months	172-814	4-84	27-108
7-9 months	217-904	11-90	34-126
10-12 months	294-1069	16-84	41-149
1 year	345-1213	14-106	43-173
2 years	424-1051	4-123	18-168
3 years	441-1135	22-159	47-200
4-5 years	463-1236	25-154	43-196
6-8 years	633-1280	33-202	48-207
9-10 years	608-1572	45-236	52-242
Adult	639-1349	70-312	56-352

Pagana KD, et al. In: *Mosby's Diagnostic and Laboratory Test Reference*. 14th ed. Elsevier; 2019: 536.

Laboratory Findings

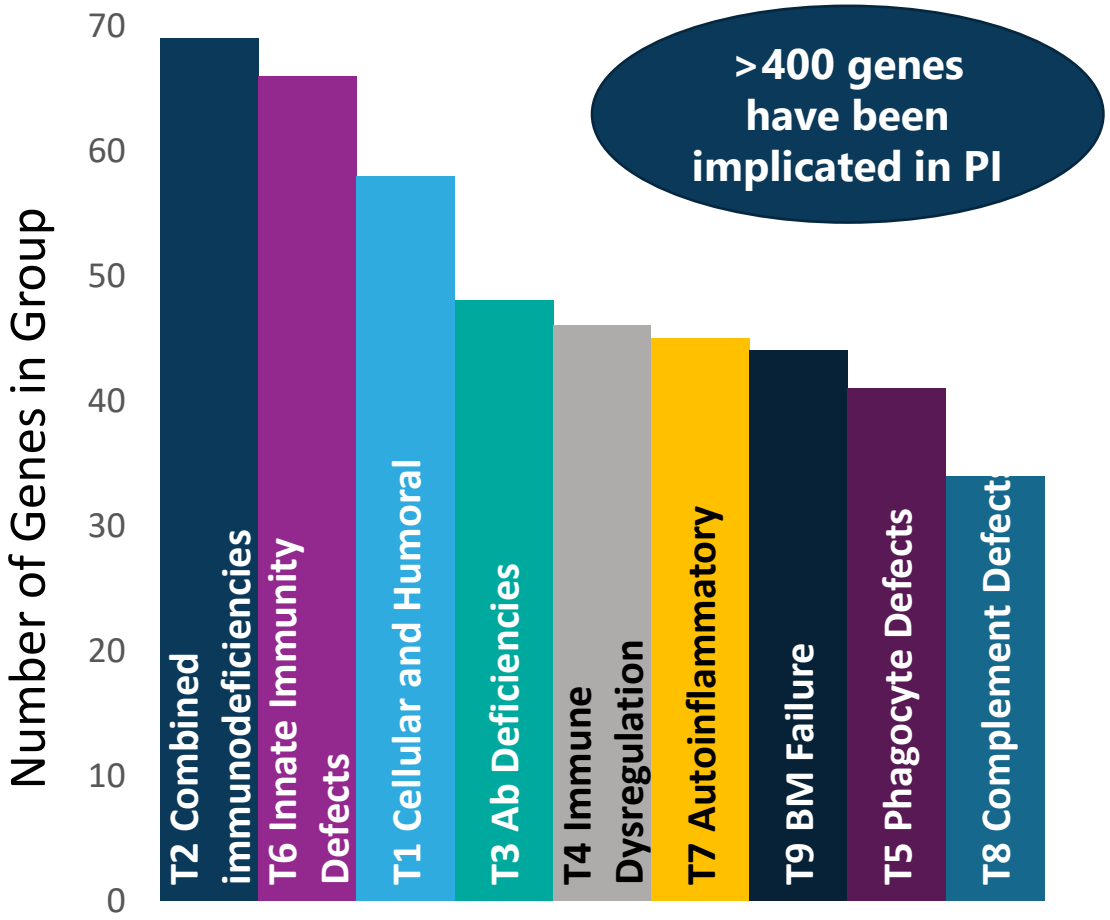
	IgA	IgD	IgE	IgG	IgM	IgG Subclasses	Vaccine Response	Other Lab Findings
SIGAD	Low/absent	-	-	Normal	Normal	-	-	-
HIGM syndrome	Low	-	Low	Low	Elevated/ normal	-	-	CD40L/CD40 deficiency
SAD	Normal	Normal	Normal	Normal	Normal	Normal	Decreased	-
THI	Normal/low	Normal/low	Normal/low	Low	Normal/low	-	Normal	-
IgG subclass deficiency	-	-	-	Normal	-	1 or more decreased levels confirmed by repeat testing	Decreased	-
HIES	-	-	Elevated	-	-	-	-	*STAT3* or *DOCK8* variants

SIGAD=selective IgA deficiency; SAD=specific antibody deficiency; THI=transient hypogammaglobulinemia of infancy; HIGM=Hyper IgM; HIES=Hyper IgE syndrome

Bonilla FA, et al. *J Allergy Clin Immunol*. 2015;136(5):1186-1205.e2078.
Locke BA, *Clin Rev Allergy Immunol*. 2014;46(2):154-168.
Yel L. *J Clin Immunol*. 2010;30(1):10-16.

Gene Panels

Expert Recommendations Suggest the Use of Gene Panels Under Special and Limited Circumstances



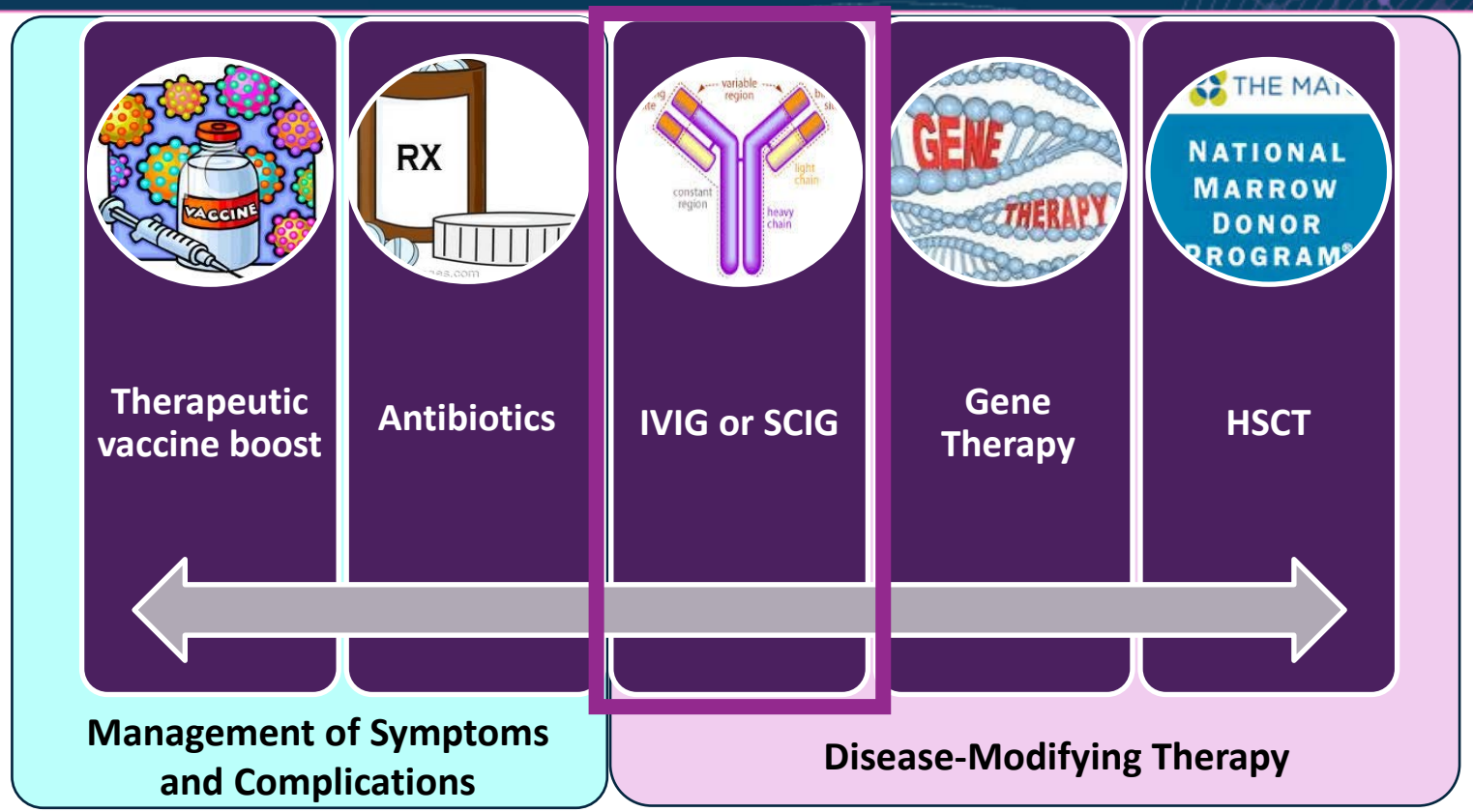
Targeted panels may be incorporated based on findings

Whole exome sequencing first

Combine **whole genome sequencing** with **RNA-sequencing** from the tissue(s) of interest

Lee H, et al. *Genet Med.* 2020 Mar;22(3):490-499.

Treatment Options



Defects in antibody production are the most common type of PI and comprise approximately 60% of such conditions encountered in clinical practice
The ***only*** treatment is ***lifetime*** administration of Ig replacement therapy

Skoda-Smith S, et al. *Ther Clin Risk Manag*. 2010;6:1–10.

Comparison of Administration Routes for Ig

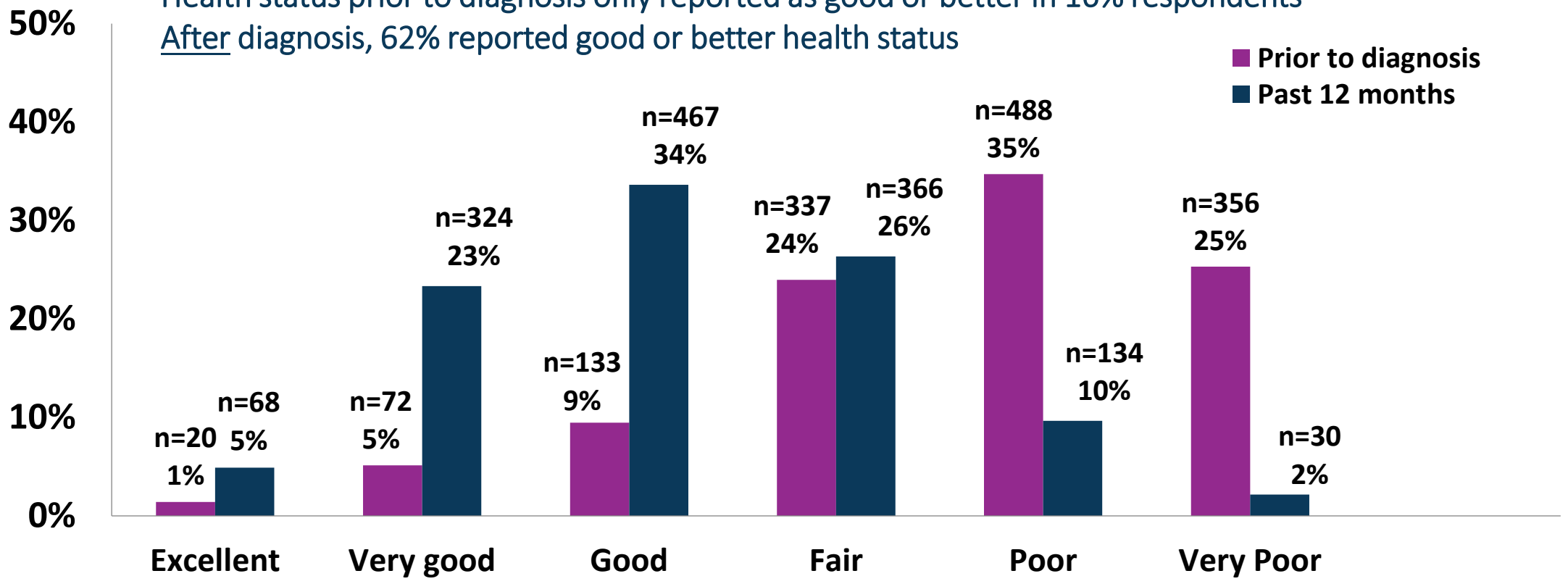
	Intravenous Immunoglobulin (IVIG)	Subcutaneous Immunoglobulin (SCIG)	Facilitated Subcutaneous Immunoglobulin (fSCIG)	Manual Push
Venous access	Yes	No	No	No
Max infusion rate	300 mL/hr	60 mL/hr	160-300 mL/hr	1-2 mL/min
Max dose/hr	30 g	6.4-8 g/site	16-30 g	NA
Infusion time/month	2.9 hr	5-6 hr	2.7 hr	3-6 hr
Training time for home	4-6 sessions over 3-6 months	4-6 sessions over 1-6 weeks	4-6 sessions over 2-6 months	4 sessions over 4 days
Peak/trough variation	Large	Minor (slightly more with fortnightly dosing)	Intermediate, dependent on treatment interval	Minor
Pump requirement	No	Yes	Yes, high volume	No

Krivan G, et al. *Am J Clin Exp Immunol*. 2017;6:76-83.
Cowan J, et al. *J Clin Immunol*. 2021;41:66-75.

Health Status Improves after Ig Therapy

Health status prior to diagnosis only reported as good or better in 16% respondents

After diagnosis, 62% reported good or better health status

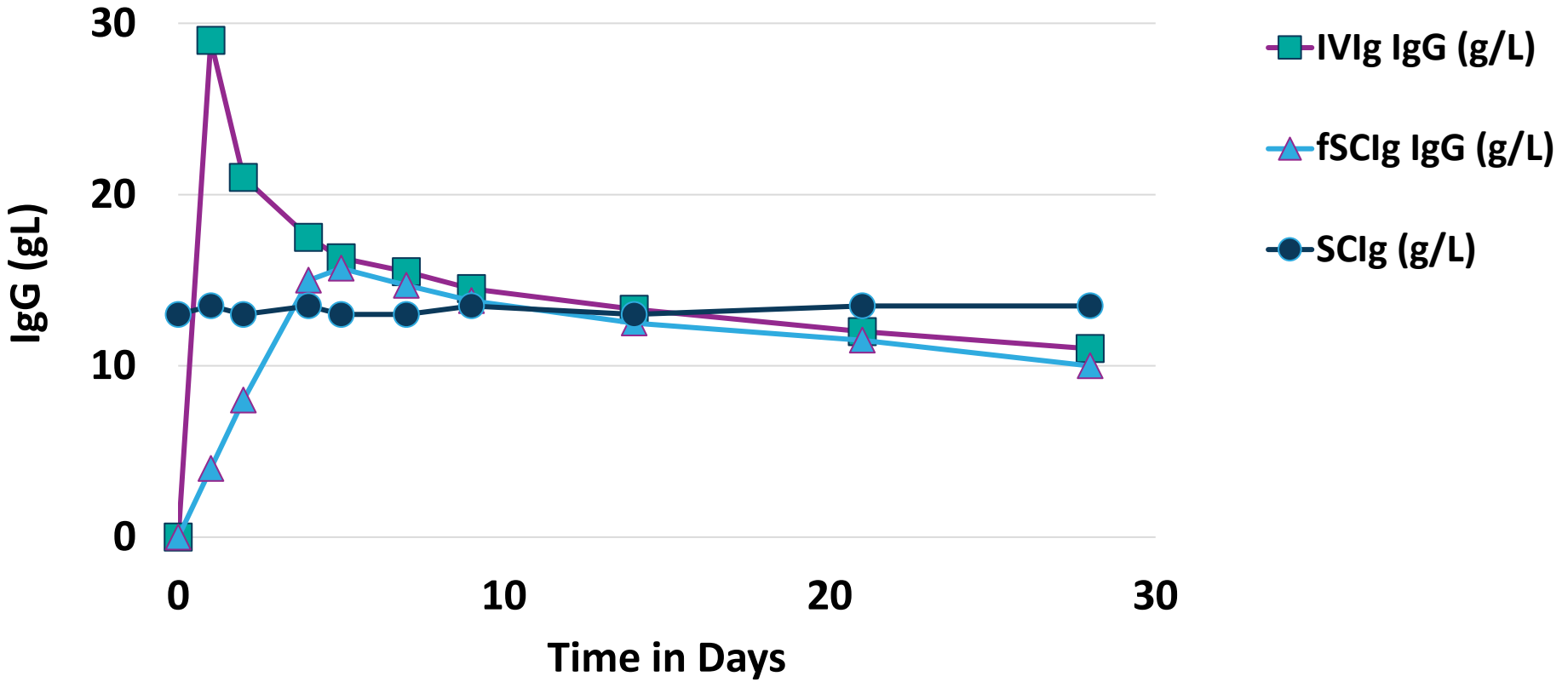


Question: Would you describe his/her health in the 12 months prior to diagnosis…? Base: Those who are currently using IVIG or SCIG Therapy N=1,406

Question: Would you describe his/her health in the past 12 months as...? Base: Those who are currently using IVIG or SCIG Therapy N=1,389

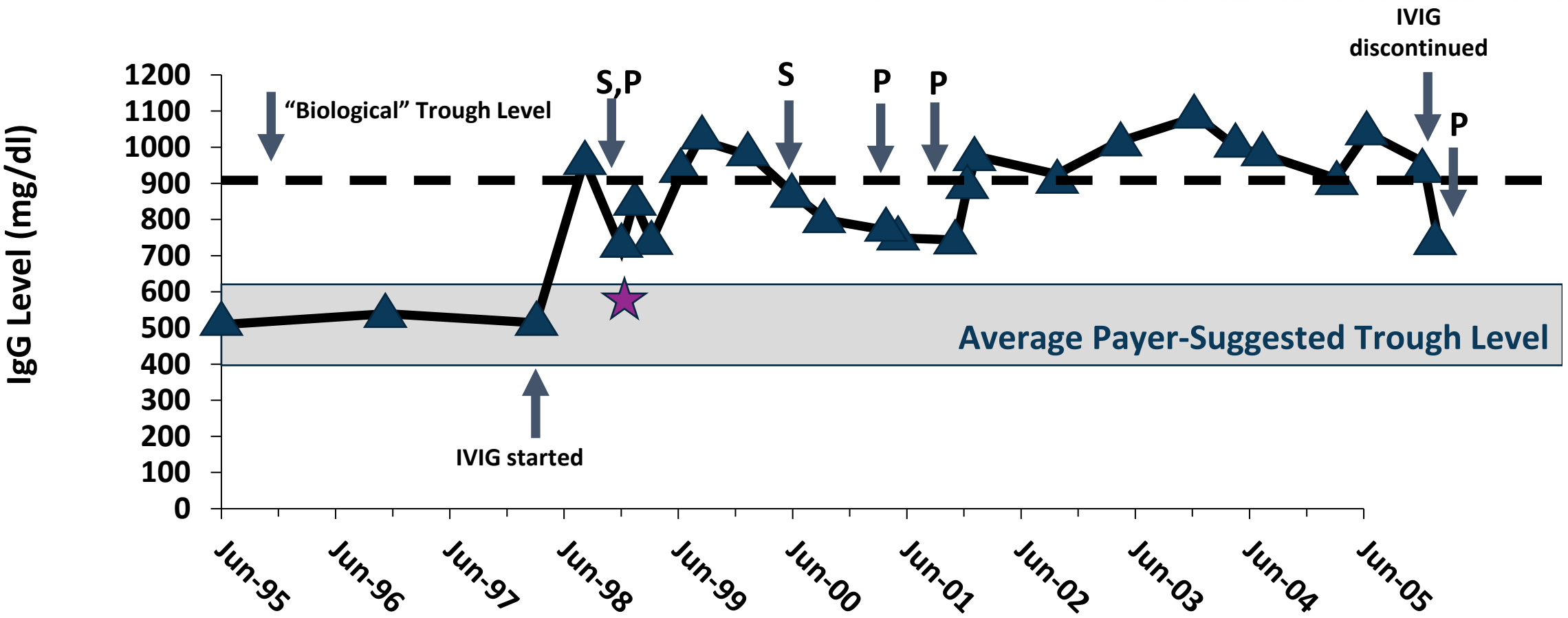
Source: 2013 IDF National Patient Treatment Survey

IVIG, SCIG, and fSCIG Pharmacokinetics



Jolles S. *Immunotargets Ther*. 2013;2:125-33.

Suboptimal Trough Levels Correlate to Infection Risk

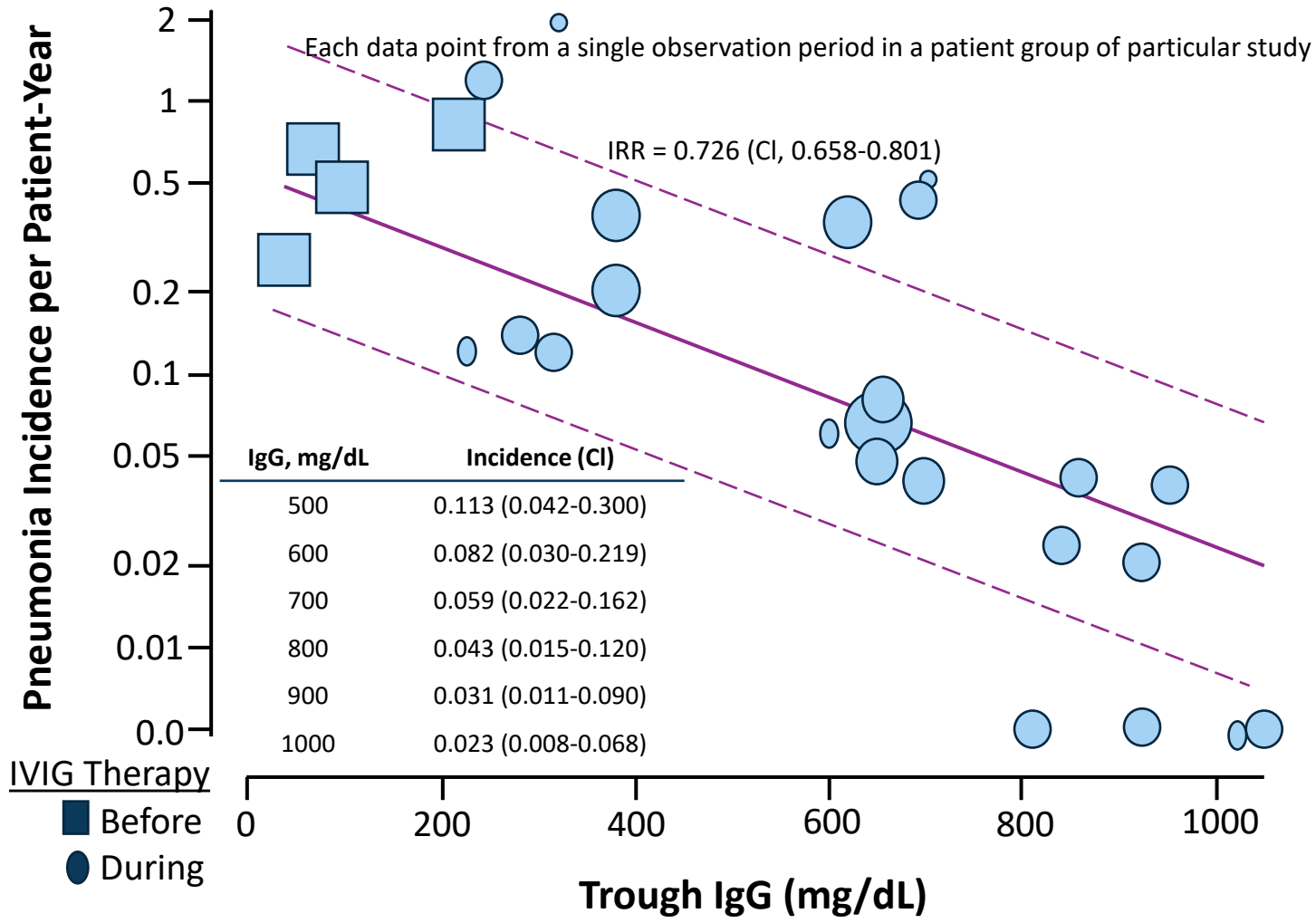


S=sinusitis, P=pneumonia

Titrate IgG trough level to clinical efficacy for an individual patient

Bonagura et al. *J Allergy Clin Immunol*. 2008;210-211.

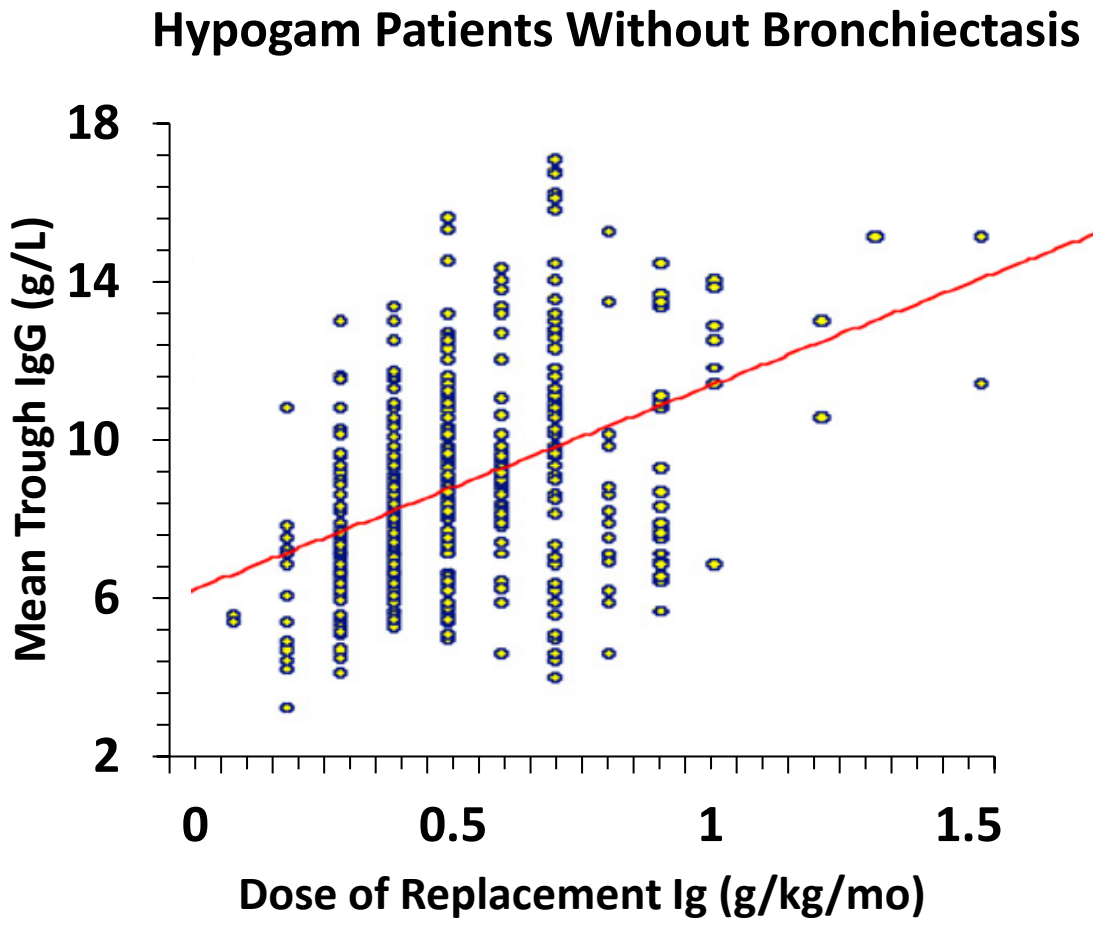
Dosing: IgG Trough Levels and Pneumonia

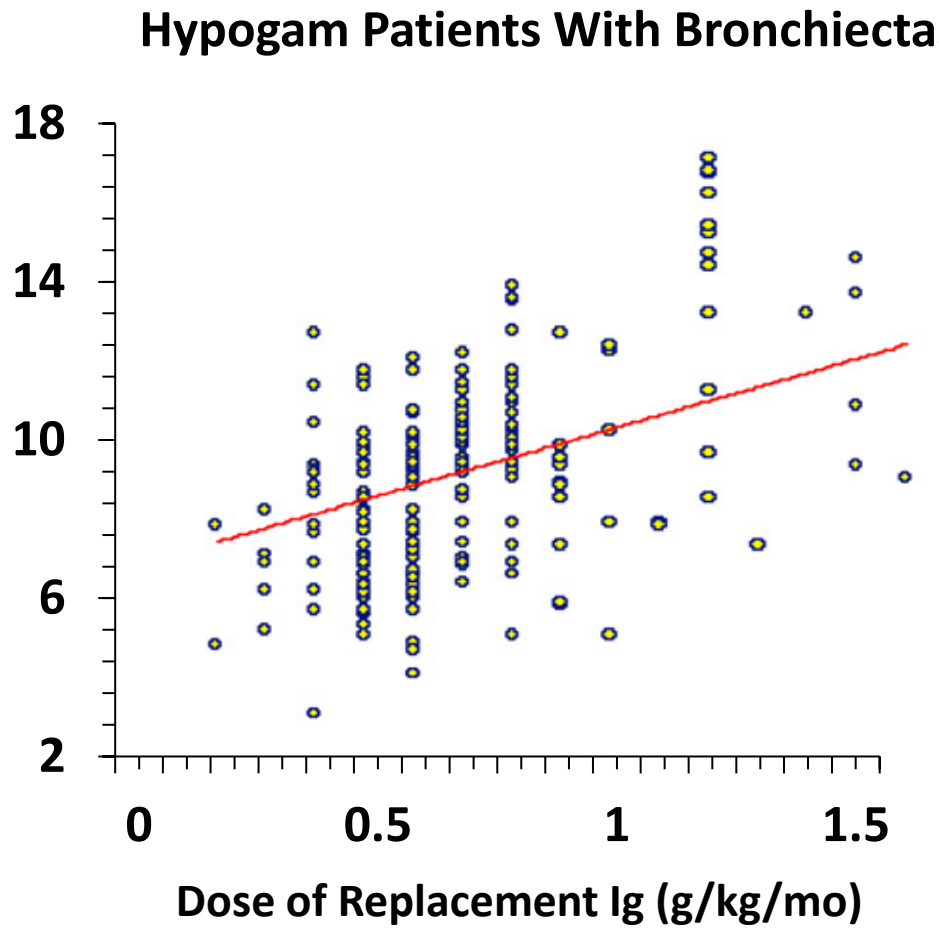


- 27% reduction in pneumonia incidence for each 100 mg/dL increment in trough IgG
- Incidence of pneumonia associated with 500 mg/dL trough levels was 5-fold that with 1000 mg/dL

Orange JS, et al. *Clin Immunol*. 2010;137:21-30.

Patients With Bronchiectasis Require Higher Doses to Maintain the Same IgG Level





Lucas M, et al. *J Allergy Clin Immunol*. 2010;125:1354-1360.

Summary

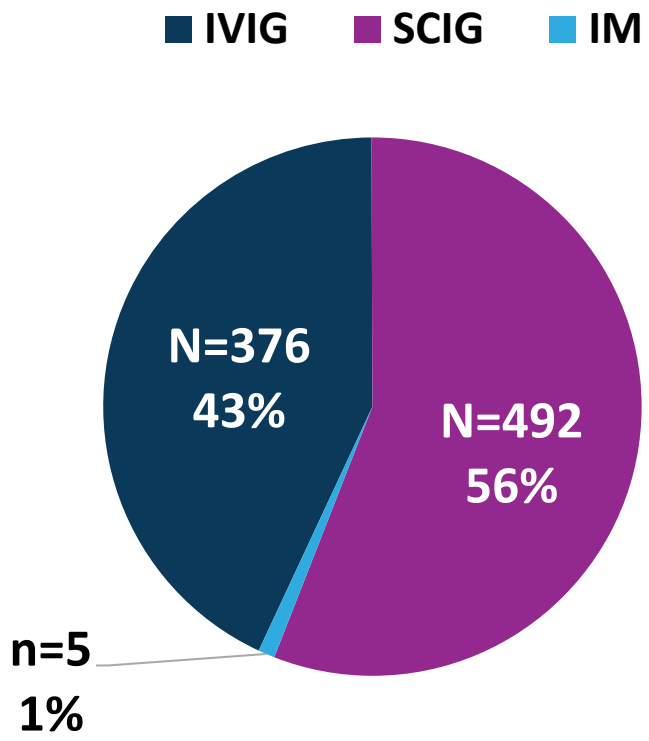
- PI represent a set of rare, chronic conditions that have a substantial effect on patient health outcomes and quality of life
- Diagnosis of PI requires a careful assessment of clinical phenotype, immunological laboratory findings, and—in some cases—genetic testing
- Immunoglobulin replacement therapy is necessary and life-saving in patients with certain PI diseases characterized by absent or deficient antibody production
- Treatment regimens should be individualized for each patient, and appropriate trough levels must be maintained for infection avoidance and optimal outcomes

Perez, et al. *J Allergy Clin Immunol*. 2017 Mar;139(3S):S1-S46.
Ducruet T, et al. *J Allergy Clin Immunol.* 2013;131(2):585-7.e1-3
Beaute J, et al. *Clin Exp Immunol.* 2010; 160(2):240-245.
Gerth WC, et al. *Allergy Asthma Clin Immunol*. 2014; 10(1):23.
Boyle ML, et al. *Pharmaceuticals Policy and Law.* 2008; 10:133-146

Optimizing Treatment Selection and Dosing for PI based on Disease Type and Patient Characteristics

James T. Kenney, RPh, MBA
President
JTKENNEY, LLC

SCIG is Used More Frequently Than IVIG



Leading reasons for switching from IVIG to SCIG include:

- Side effects
- Infusion schedule/convenience
- Provider difficulty finding a vein
- Prescriber recommendation
- Significant travel required for treatment

Question: Is the patient currently being treated with IM, IVIG or SCIG? n=873
Base: All Persons with PI who Currently Receive Ig Replacement Therapy

Source: IDF 2017 National Patient Survey

Variables Affecting Patient Preference

Practical factors	IVIG	SCIG	fSCIG
Site of care	Home or infusion center	Home	Home or infusion center
Medical supervision	Yes	Yes	Yes
Ongoing nurse support	Yes	No	+/-
# of needle sticks	One	1 to multiple sites	1-2
Dexterity	Not so important	Important	+/-
Side effects	Fewer local AEs	Fewer systemic AEs	Fewer systemic AEs
Compliance	"built in" safety	Up to the pt	Up to the pt (+/-)
Length of administration (per infusion)	1-4 hours	~1 hour	
Independence	Rely on nurse or center	Rely on self	
Portability	Limited	Yes	
School/work absence	Likely	Less likely	

Adapted from Jolles S, et al. British Society for Immunology. *Clin Exp Immunol*. 2014;179:146-160.

Guiding Principles of Ig Therapy that Shape Payer Policy

1. **Indication-** replacement therapy for patients with absent or deficient antibody production
2. **Diagnoses** – there are many PI diagnoses for which Ig is indicated and recommended. Many have low total levels of IgG, but some have a normal level with documented specific antibody deficiency
3. **Frequency of Ig Treatment** - Ig is indicated as continuous replacement therapy for PI and should not be interrupted when a definitive diagnosis is made
4. **Dose** - Ig is indicated for patients with primary immunodeficiency at a starting dose of 400-600 mg/kg every 3-4 weeks for IVIG administration and 100-200 mg/kg every week for SCIG administration

IDF. Clinical Update in Immunoglobulin Therapy for Primary Immunodeficiency Disease.
Ballow M. *Ann Allergy Asthma Immunol*. 2013;111(6 Suppl):S2-5.

Guiding Principles of Ig Therapy that Shape Payer Policy (cont.)

5. **IgG Trough or Steady State Levels** - can be useful in some diagnoses to guide care but should NOT be a consideration for access to IVIG therapy

6. **Site of Care** – the decision to infuse Ig in a hospital, hospital outpatient, community office, or home-based setting is based upon clinical characteristics

7. **Route** – the **r**oute of Ig administration is based upon patient characteristics

8. **Product** – Ig is not a generic drug and Ig products are not interchangeable. A match to patient characteristics is a consideration for patient safety and a change of product should occur in consultation with the prescriber

Orange J. Clinical Update in Immunoglobulin Therapy for Primary Immunodeficiency Disease. Immune Deficiency Foundation. Published March 2011. https://primaryimmune.org/sites/default/files/publications/Clinical-Update-in-Immunoglobulin-Therapy-for-Primary-Immunodeficiency-Diseases_1.pdf
Ballow M. *Ann Allergy Asthma Immunol*. 2013;111(6 Suppl):S2-5.

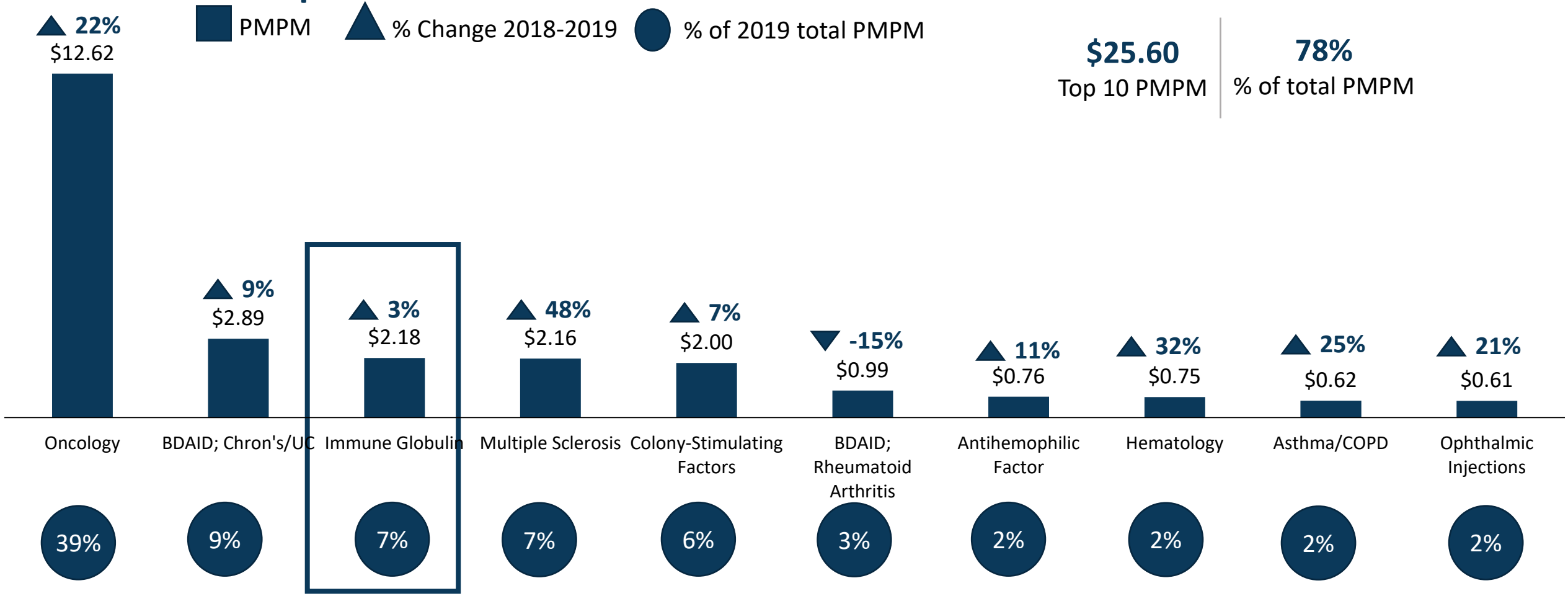
Appropriate Treatment with Ig Therapy Can Result in Cost Savings via Decreased Resource Utilization

Condition	Pre-Dx Average No. of Episodes	Pre-Dx Cost per Episode	Pre-Dx Annual Cost	Post-Dx Average No. of Episodes	Post-Dx Cost per Episode	Post-Dx Annual Cost	Post-Dx Average Annual Savings
Persistent otitis media	4.2	$528	$2217	1.6	$528	$845	
Serious sinus and upper respiratory infections	4.6	$1125	$5175	2.1	$1125	$2362	
Viral infections	3.7	$1275	$4717	1.4	$1275	$1785	
Acute bronchitis	3.1	$1700	$5270	0.8	$1700	$1360	
Bacterial pneumonia	2.8	$3552	$9945	0.6	$3552	$2131	
Chronic obstructive pulmonary disease and bronchiectasis	4.3	$3165	$13,609	1.4	$3165	$4431	
Hospitalization days	19.8	$2480	$49,104	3.1	$2480	$7688	
Physician/ED visits	70.8	$180	$12,744	11.7	$180	$2106	
Days on antibiotics	1662	$10	$1662	72.8	$10	$728	
School/work days missed	33.9	$195	$6610	8.9	$195	$1735	
Total cost annually per patient without IgG			$111,053			$25,171	$85,882 annual savings per patient per year without IgG
Average annual cost of IgG						$30,000	
Total cost savings annually including 100% on IgG (actual total 25.6%)							$55,882 annual savings per patient per year without IgG

Vaughan LJ. *Am J Manag Care*. 2019 Jun;25(Suppl 6):S105-S111.

Ig is a Top-10 Medical Benefit Drug Category Across All Lines of Business

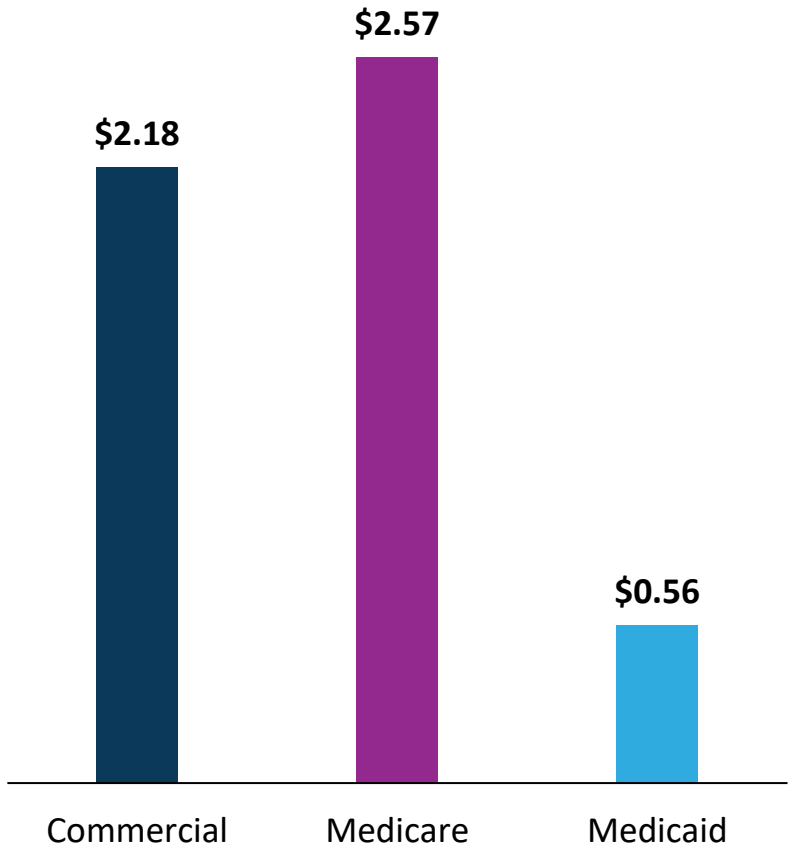
Commercial Population



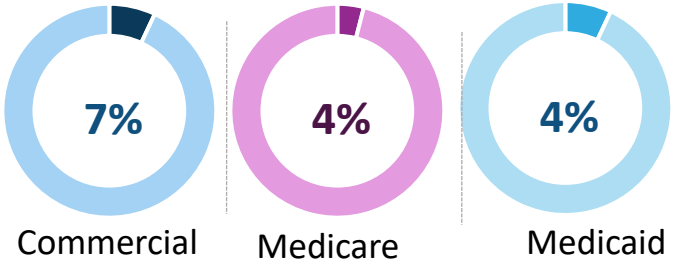
Magellan Rx Medical Pharmacy Trend Report.. Magellan Rx Management. Published 2021. https://issuu.com/magellanrx/docs/mptr20_050421_weboptimizedwithlinks?fr=sOGUyMTM2MDc3MDU.

Ig Category Spend/Trend and Forecast Across All Lines of Business

2019 CATEGORY PMPM



2019 % OF MEDICAL DRUG SPEND



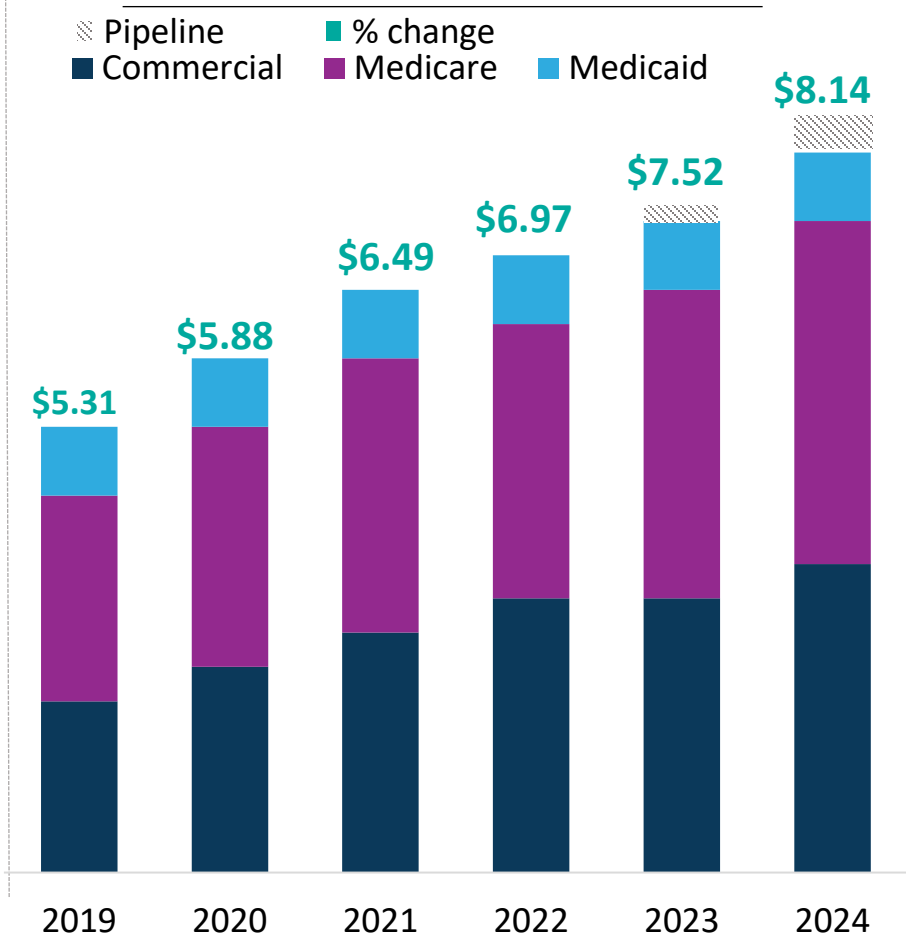
2018-2019 CATEGORY PMPM TREND

Commercial	Medicare	Medicaid
3%	-22%	-6%

2019 COST PER CLAIM

Commercial	Medicare	Medicaid
$3,159	$2,454	$2,331

FORECAST

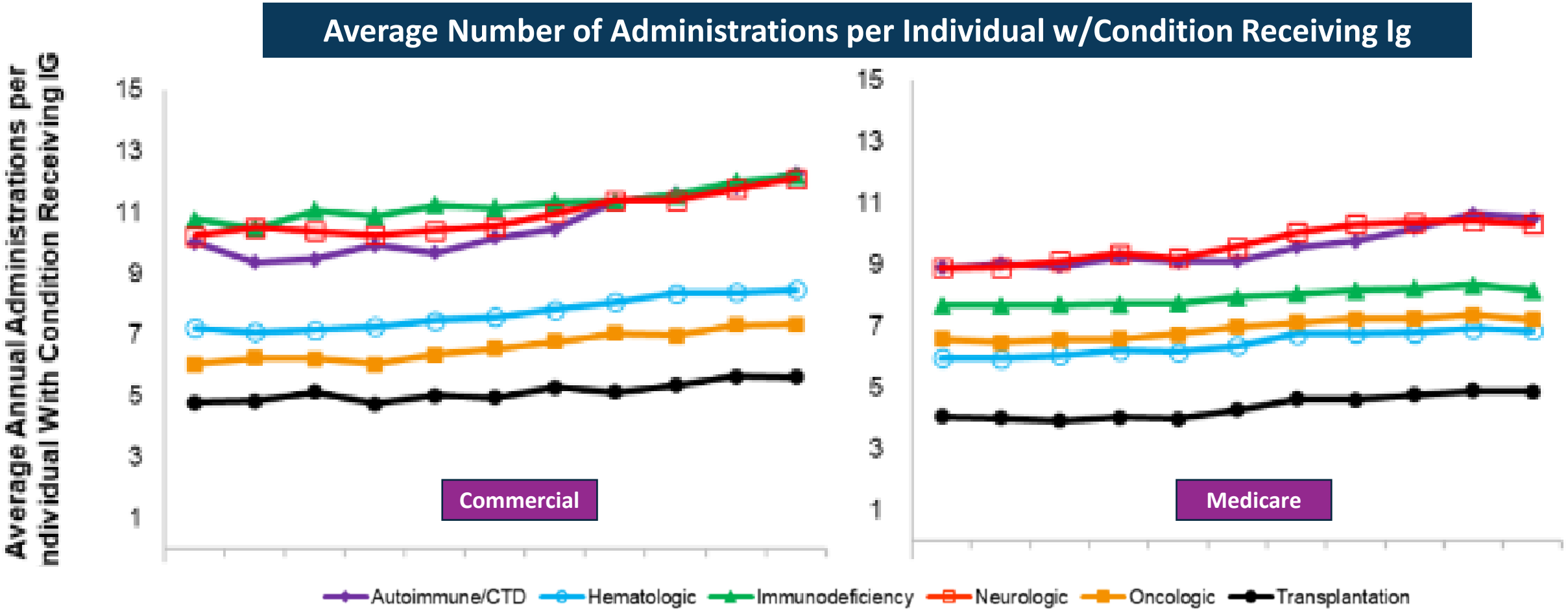


Magellan Rx Medical Pharmacy Trend Report.. Magellan Rx Management. Published 2021. https://issuu.com/magellanrx/docs/mptr20_050421_weboptimizedwithlinks?fr=sOGUyMTM2MDc3MDU.

PI is Only One of Over 40 Diseases that Use Ig and One of Only Seven FDA-approved Uses of Ig

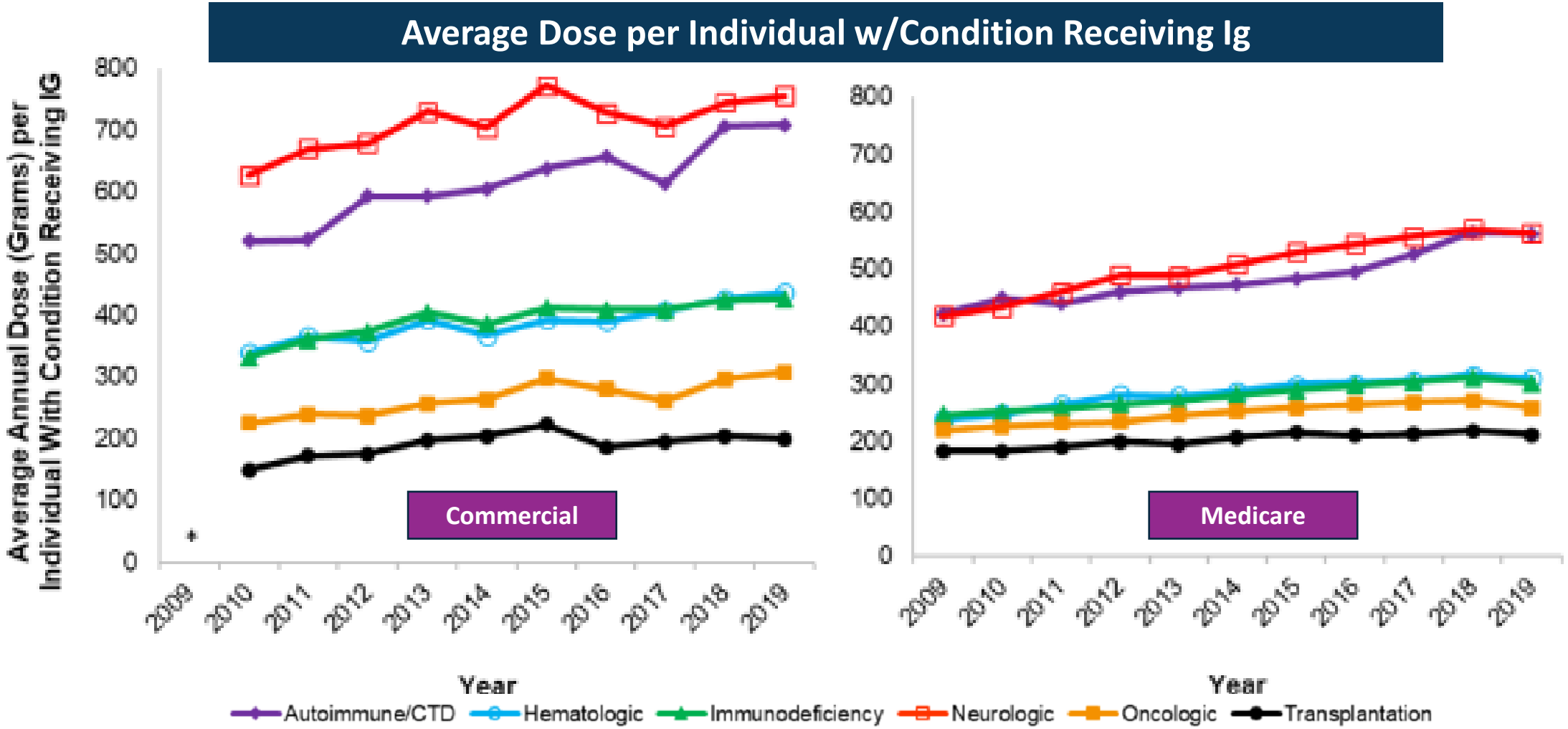
- Other approved uses include chronic inflammatory demyelinating polyneuropathy (CIDP), idiopathic thrombocytopenic purpura (ITP), Kawaski syndrome, chronic B-cell lymphocytic leukemia, dermatomyositis, and multifocal motor neuropathy
- Upwards of 100 off-label uses for Ig include multiple sclerosis, graft-versus-host disease in transplant recipients, prevention of antiphospholipid syndrome in miscarriage, and Guillain-Barré syndrome

PI Accounts for a Modest Share of Ig Administrations Relative to Other Conditions



CBER Surveillance Program Biologics Effectiveness and Safety (BEST) Initiative. FDA. Published 2022. https://bestinitiative.org/wp-content/uploads/2022/04/Assessment-of-Immune-Globulin-Utilization-in-Commercially-insured-and-Medicare-Populations.pdf.

Autoimmune and Neurologic Conditions Account for Higher Average Ig Doses than PI



CBER Surveillance Program Biologics Effectiveness and Safety (BEST) Initiative. FDA. Published 2022. https://bestinitiative.org/wp-content/uploads/2022/04/Assessment-of-Immune-Globulin-Utilization-in-Commercially-insured-and-Medicare-Populations.pdf.

A Multitude of Indicated and Off-label Uses for Ig Has Drawn Increased Attention from Payer Stakeholders

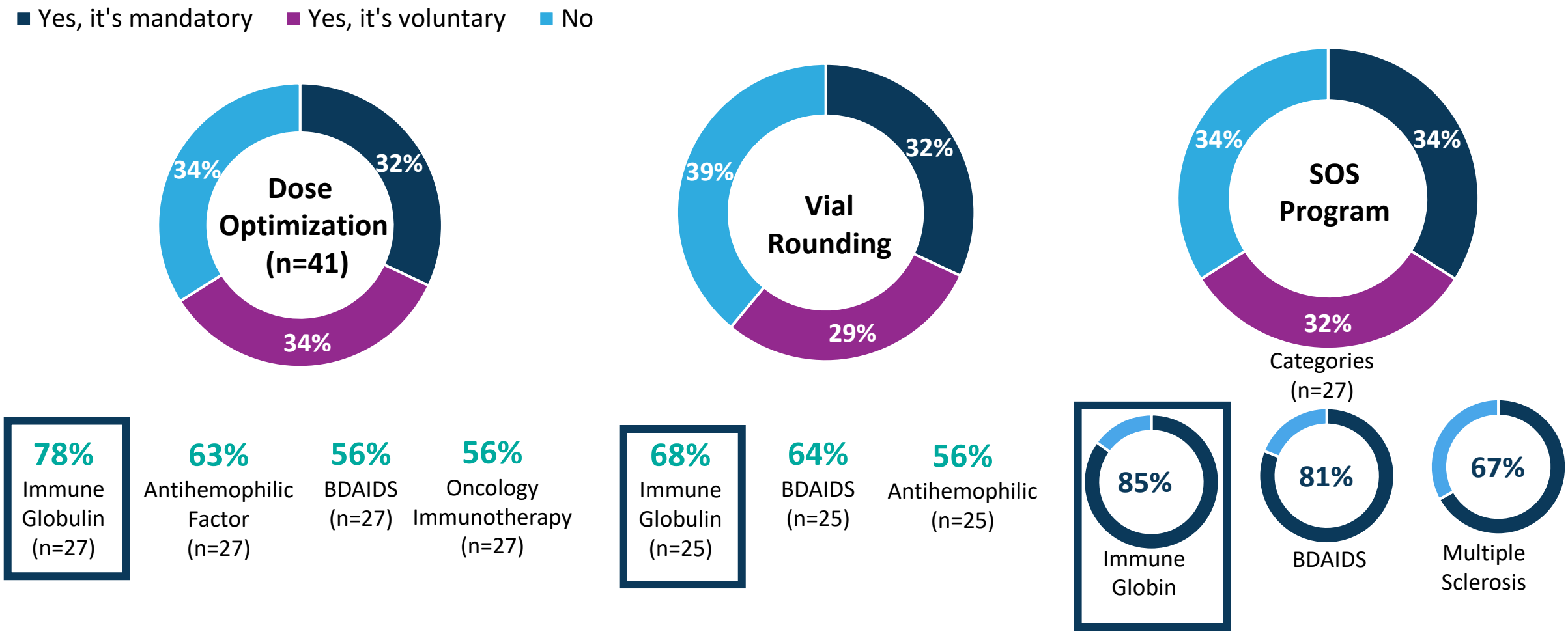
- Specialty drugs had already become an area of increased focus for payer management efforts, due to the high cost and increased utilization trend
- Ig therapies, which carry a high potential for inappropriate and/or off-label use, are one area receiving enhanced attention in terms of management interventions
- In PI, where Ig replacement therapy serves as a lifelong, lifesaving therapy and further represents the only available pharmacologic treatment modality, these management efforts must be carefully managed

Payers Must Balance Ig Coverage Policies with Patient Access in the Management of PI

Various products and modes of administration available on formulary

Restrictive UM interventions that disrupt access and continuous treatment

In Addition to Prior Authorization, Payers Use Several Means to Manage Ig-Related Utilization and Spend



Magellan Rx Medical Pharmacy Trend Report. Magellan Rx Management. Published 2021. https://issuu.com/magellanrx/docs/mptr20_050421_weboptimizedwithlinks?fr=sOGUyMTM2MDc3MDU.

Cost Sharing Considerations

- In the wake of reform legislation and tighter health care budgets, plans and employer sponsors are increasingly shifting a greater proportion of costs to members
- With copays as low as $30 demonstrating an adverse effect on adherence even in immediately life-threatening conditions such as cancer, payers must be ever aware of the unintended consequences of such measures including prescription abandonment by patients

2021 Employer Health Benefits Survey. Kaiser Family Foundation. https://www.kff.org/report-section/ehbs-2021-section-8-high-deductible-health-plans-with-savings-option/.
Neugut AI, et al. *JAMA Oncol.* 2016;2(10):1326–1332.

Site-of-Care/Channel Management Considerations

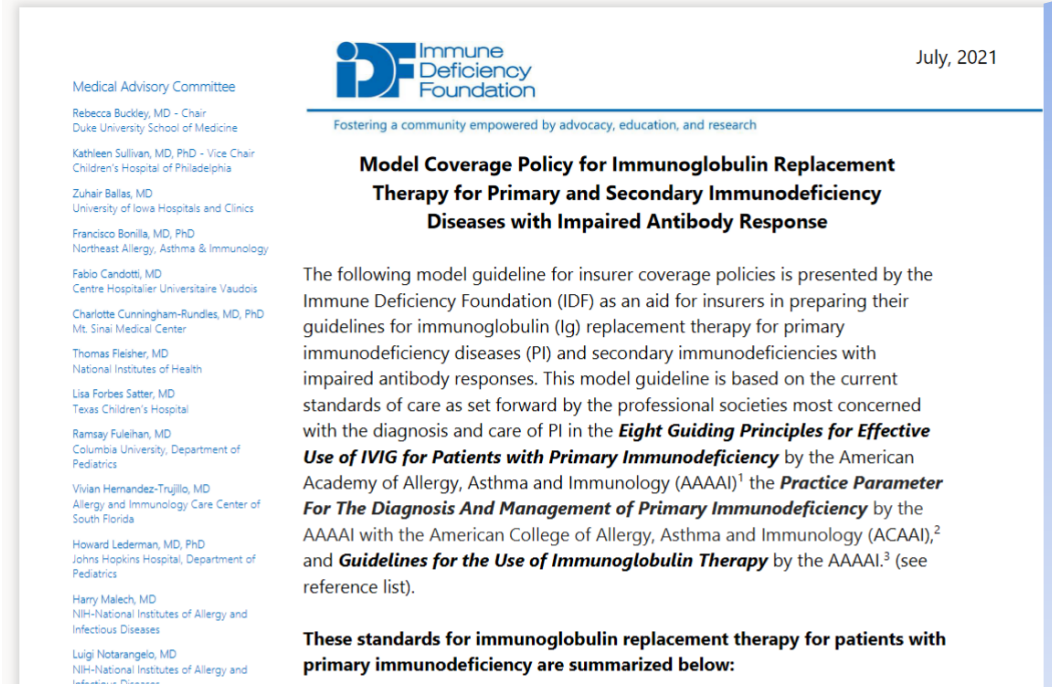
- Certain settings, namely those outside of hospitals/facilities, carry inherently lower costs in terms of drug administration.
  - Not all sites of care are appropriate for all patients
- Distribution channel management interventions that drive care to lower-cost sites of care are value based in terms of costs to both the plan and member.
  - Patients' individual clinical needs and preferences must be taken into consideration to promote adherence

Employee Benefits Research Institute. https://www.ebri.org/docs/default-source/ebri-issue-brief/ebri_ib_536_locationx3-19aug21.pdf?sfvrsn=cf6c3b2f_4.

Emerging Strategies May Play a Role in Future Ig Replacement Management Initiatives

- Value-based Benefit Design
- PBM and Specialty Pharmacy-driven Management Programs
- Bundled Payments
- Better Care Coordination

Patient Advocacy Organizations Have Developed Best Practices in Model Ig Coverage Policy for Payers to Reference



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Immune Deficiency Foundation

July, 2021

Fostering a community empowered by advocacy, education, and research

Model Coverage Policy for Immunoglobulin Replacement Therapy for Primary and Secondary Immunodeficiency Diseases with Impaired Antibody Response

The following model guideline for insurer coverage policies is presented by the Immune Deficiency Foundation (IDF) as an aid for insurers in preparing their guidelines for immunoglobulin (Ig) replacement therapy for primary immunodeficiency diseases (PI) and secondary immunodeficiencies with impaired antibody responses. This model guideline is based on the current standards of care as set forward by the professional societies most concerned with the diagnosis and care of PI in the ***Eight Guiding Principles for Effective Use of IVIG for Patients with Primary Immunodeficiency*** by the American Academy of Allergy, Asthma and Immunology (AAAAI)[1] the ***Practice Parameter For The Diagnosis And Management of Primary Immunodeficiency*** by the AAAAI with the American College of Allergy, Asthma and Immunology (ACAAI),[2] and ***Guidelines for the Use of Immunoglobulin Therapy*** by the AAAAI.[3] (see reference list).

These standards for immunoglobulin replacement therapy for patients with primary immunodeficiency are summarized below:

Insurers should cover IVIG or SCIG as medically necessary for the PI listed given the following:

- The specific criteria by medical condition as listed are met.
- The dosage, frequency, site of administration, and duration of therapy are reasonable, clinically appropriate, and supported by evidence-based literature.
- The choice of product and route of administration is determined by the prescribing physician in consultation with the patient.
- Switching patients from a well-tolerated IgG product to a different product should be undertaken only after careful consideration of risks and benefits by both the patient and the prescribing physician.

Model Coverage Policy for Immunoglobulin Replacement Therapy for Primary and Secondary Immunodeficiency Diseases with Impaired Antibody Response. Immune Deficiency Foundation https://primaryimmune.org/sites/default/files/MAC%20Model%20Coverage%20Policy%20for%20Ig%20with%20Appendix%207.22.21.pdf.

Summary

- The safe and effective use of Ig requires attention to numerous issues that relate to individual patient characteristics, site of care, and product
- Ig represents a driver in the specialty drug spend but can result in total cost savings when used appropriately in the management of PI
- Payers use prior authorization by label indication to reduce off-label prescribing of IG, but also incorporate more sophisticated interventions such as vial rounding, dose optimization, and SOS
- It is crucial that specialty drug coverage policies and utilization management interventions take into consideration the importance of individualized therapy in PI

Case-Based Presentation:

Medical and Pharmacy Management Strategies to Enhance PI Patient Outcomes in a Managed Care Setting

Background

18-year-old male

Starting college in the fall

History of upper respiratory tract infections, sinusitis, recurrent pneumonia

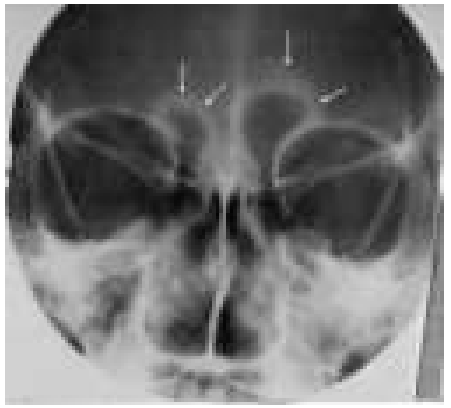
Presentation

January 2017

Patient complains to his primary care physician that he is "always catching every cold going around school"

In addition, he has had recurrent sinusitis as well as three bouts of pneumonia in the past two years needing multiple rounds of antibiotics

He also voices concern that he is often fatigued and avoids going out in public during flu season for fear of getting sick again



Physician refers him to an immunologist, who finds that all of his Ig levels are normal

Diagnostic Challenges

The immunologist administers a pneumococcal vaccine test and the patient developed low, but near-normal, antibodies

February 2018

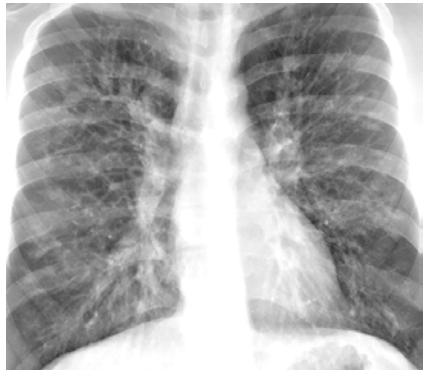
The immunologist suspected a diagnosis of specific antibody deficiency (SAD) despite the suboptimal vaccine response

The immunologist orders another pneumococcal vaccine test, but coverage is denied

March 2018

Further Complications and Diagnosis

Two months later, the patient presents with another upper respiratory infection; Chest x-ray reveals bronchiectasis



The second vaccine test is approved and shows persistent low levels of antibodies indicative of SAD

May 2018

The immunologist submitted another claim for a pneumococcal vaccine test, providing more information on the patient's history

June 2018

Initial Treatment

August 2018

The patient is prescribed prophylactic antibiotics but continues to suffer from sinusitis

A prescription of IVIG by his immunologist is denied by the insurer

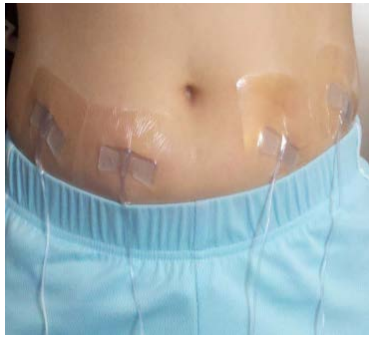
September 2018

After an appeal citing clinical guideline support of IVIG in the treatment of SAD the claim is approved after a subsequent denial/appeal due to weight-based dosing

Refining Treatment and Encountered Coverage Issues

November 2018

The patient complains it is difficult making infusion appointments due to his move to a college in a rural town, and after an allergic reaction to his initial IVIG product, the patient's immunologist prescribes SCIG therapy



February 2019

The SCIG prescription was well tolerated and kept the patient free from infection for several months

October 2019

Exclusion of the SCIG product from formulary caused a disruption in therapy, resulting in a reoccurrence of sinusitis, after which the patient was switched back to IVIG which was not well tolerated

Resolution and Conclusion

January 2020-Present

- The immunologist appealed the change in coverage by providing a log of the patient's adverse reaction to the new IVIG product, as well as a detailed history including the past IVIG failure
- Eventually the coverage of the patient's preferred SCIG product was approved, and the patient has been free from infection for more than 18 months
- He remains enrolled in college and is doing well in his coursework

Q&A and Discussion

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How to Claim Credit

- **Option 1:** Complete the paper-based evaluation and turn it in at the end of the meeting.
- For Pharmacists: You will receive an email from CEcertificate@pimed.com within 3-4 weeks with a link and directions to submit your credit to the NABP CPE Monitor Service.
- **Option 2:** OR, complete the evaluation online. **Please do NOT do both.**
- Go to www.cmeuniversity.com and register or login.
- Type in **17369** at the top of the page under "**Find Post-Test/Evaluation by Course**" and click enter.

Pharmacist have up to 30 days to complete the evaluation and claim credit for participation so that information can be submitted to CPE Monitor as required.

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