



Electronic Medical Records (EMRs) in Practice: Primary Immunodeficiency (PI)

Unlock EMR Solutions to Your PI Challenges



Table of Contents

Introduction	3
Scenario 1: Identifying Potentially Undiagnosed Patients	4
Scenario 2: Utilizing Additional Support and Resources	6
Scenario 3: Providing Patients With Additional Support.....	8
Scenario 4: Ensuring Adherence to Ig Use Protocols	10
Scenario 5: Ensuring Prescriptions Are Filled In-Network	12
Scenario 6: Ensuring Referrals Stay In-Network	14
Scenario 7: Providing Best-in-Class Care.....	16

Introduction

Primary Immunodeficiency (PI) is a group of more than 350 rare genetic disorders involving one or more intrinsic defects in the human immune system.¹ PI is underdiagnosed, with an average time to diagnosis of 15 years.² Delays in diagnosis lead to significant health complications and healthcare resource utilization.^{3,4}

Prior to diagnosis, patients with PI experience a greater number of acute and severe infections and an increased number of days with chronic infections, increased antibiotic usage, and additional physician, hospital, and emergency department visits and days in the hospital.⁴ After diagnosis, patients with PI require lifelong care and treatment.⁵

This guide highlights how the use of your electronic medical record (EMR) system can solve a myriad of PI challenges and barriers to help your patients and organization. The scenarios and blueprints showcased in this guide help:

- Identify challenges
- Provide high-level direction on how to utilize standard reporting tools
- Monitor dosing and utilization protocols
- Improve adherence
- Track in-network Rx fills and in-network referrals

This guide serves as an example blueprint and is not a step-by-step programming or implementation guide. This is only intended to help with potentially setting up the suggested solutions in an EMR system and to help facilitate implementation at different levels. The suggested solutions are designed to use tools and functionality that exist in the typical hospital EMR. Because all organizations and systems are different, you should consult your system and subject matter experts to determine if a solution can be implemented and is right for your organization.

Scenario 1: Identifying Potentially Undiagnosed Patients

Objective

To identify potentially undiagnosed patients with PI across your network by developing a report generated from the EMR that can be delivered and used periodically.



Hypothetical Situation

- Dr. Smith is the head of her hospital department and works on a committee that helps oversee quality for her hospital's network
- She believes that some of the network's patients might have PI, but have not yet been diagnosed
- She is aware that PI is rare and many clinicians can miss or mistake the symptoms of PI for something else entirely, or as the root cause of other symptoms
- However, she also knows the signs and symptoms of patients who have PI and wants to use the EMR to search for and find patients who fit this profile across her hospital's network

Did
You
Know?

PI is more common than you may think, with **250,000** diagnosed^{6,a} and a prevalence of **1:1200**^{6,b}

Patients with PI are often treated for symptoms (eg, pneumonia, bacterial or recurring infections), while the **underlying cause goes unrecognized**^{7,8}

Early detection and **diagnosis can improve** patient satisfaction and quality of life⁹

Fewer readmissions and better patient satisfaction can lead to improved accountable care organization (ACO) scores¹⁰

Not diagnosing a patient with an underlying PI defect represents an annual negative economic impact of **\$85,882** per patient to the healthcare system¹¹

- Undiagnosed patients with PI cost the US healthcare system over **\$40 billion** annually⁵

^a According to an estimate by the Immune Deficiency Foundation.

^b According to an estimate by the National Institutes of Health.

Solution Blueprint: How to Use an EMR System to Identify Patients

The typical hospital EMR allows you to search for patients who meet certain criteria.

Steps	What to search
1. Locate the reporting or search tool that allows you to search for patients within your EMR	
2. Limit the time period you are searching	<p>For example, if today were January 30, 2020, and you wanted to search for 1 year in the past, you would search January 30, 2019 through January 30, 2020.</p> <p>Use dynamic dates if your system allows.</p>
3. Set the patient population you wish to search	<p>The typical hospital EMR has parameters or criteria that allow your search to filter results.</p> <p>Searching larger patient populations—such as across your entire network—will yield more complete results, but depending on your organization's structure or policies, you may wish to limit your search.</p> <p>The logic or selection options in your EMR may resemble “all patients,” “my patients,” “immunology patients,” or allow you to select patient lists based on other criteria such as location.</p>
4. Exclude patients with an existing PI diagnosis	<p>To exclude patients already diagnosed with PI, set your search to find patients who have not been diagnosed with the following International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) codes that may be used for PI, including¹²:</p> <p>D15, D46.9, D70.0, D70.8, D71, D72, D76.1, D80.0, D80.1, D80.2, D80.3, D80.4, D80.5, D80.6, D80.7, D80.8, D80.9, D81.0, D81.1, D81.2, D81.3, D81.4, D81.5, D81.6, D81.7, D81.89, D81.9, D82.0, D82.1, D82.2, D82.3, D82.4, D82.8, D82.9, D83.0, D83.1, D83.2, D83.8, D83.9, D84.1, D84.9, D89.9, G11.3</p> <p>Some EMR search tools allow you to use “AND” or “OR” logic</p> <ul style="list-style-type: none"> ■ If your EMR allows this, use “OR” logic for this parameter ■ If your EMR does not allow this type of logic, you may also search each existing diagnosis listed above separately for each diagnosis you wish to search in the next step
5. Include patients with a recent medical history that could indicate undiagnosed PI	<p>Set your search to find patients who have had more than one diagnosis or occurrence of the following ICD-10 codes¹²:</p> <ul style="list-style-type: none"> ■ Bronchiectasis: J47 ■ Meningitis: G00, G03 ■ Sepsis: A40, A41, R65 <p>You may also set your search to find patients who have 2 or more diagnoses or occurrences of the following ICD-10 codes¹:</p> <ul style="list-style-type: none"> ■ Otitis media: H65,^c H66,^c H67^c ■ Sinusitis: J01,^c J32 ■ Bronchitis: J20,^c J40, J41, J42 ■ Pneumonia: J13,^c J14,^c J15,^c J16,^c J18,^c Z87.01 ■ Diarrhea with weight loss: K59.1, R19.7, R63.4 ■ Recurrent abscess of skin or internal organs: J39.1, K20.8, K51.414, K57.0, K61, K63.0, K65.1, K75.0, L02.91 ■ Septicemia: R65.2 ■ Thrush: B37.0^c ■ Failure to gain weight (child): R62.51 ■ Recurrent viral infections: A63.0,^c B00,^c B07,^c J00^c <p>If your EMR allows “AND” or “OR” logic, use “OR” logic for this parameter.</p> <p>If your EMR does not allow this type of logic, you may also search for the diagnosis or occurrence listed above separately for each diagnosis you wish to search in the previous step.</p>

^c For acute forms of these diagnoses, the patient should have experienced recurrent episodes.

Identification of patients for the evaluation of an antibody production defect should be based on clinical judgment.

More specific diagnosis codes are available at www.cms.gov.

Because all organizations and systems are different, you should consult your system and subject matter experts to determine if a solution can be implemented and is right for your organization.

Scenario 2: Utilizing Additional Support and Resources

Objective

To provide standardized education tools and resources to be shared with the patient who was recently documented by an ICD-10 code for PI in their electronic chart. The patient may have recently been diagnosed with PI, was in the office for a recent visit, or visited the office for a chronic problem.



Hypothetical Situation

- Dr. Smith has just diagnosed a patient with PI
- However, there are no standard educational materials that are specific to PI available in the EMR for clinicians to share with patients
- Dr. Smith is aware that you can create standardized educational content in your EMR, which can be automatically added into a workflow—so that clinicians can educate patients on various diseases, injuries, and topics—based on a patient’s diagnosis
- Currently, the healthcare network does not use or is in the process of purchasing patient education content from a third party, but is interested in developing a standardized set of patient education materials to be automatically loaded into a clinician’s workflow for patients with PI

Did
You
Know?

PIs are **rare conditions**, and often providers may not have all the answers patients need⁹

As a result, newly diagnosed patients **may not receive adequate education** about their PI⁹

Patient education tools and resources help patients⁵:

- Understand their condition
- Learn about therapy
- Learn how to seek physiological and social support
- Gather information on living with PI through different stages in life

Solution Blueprint: Providing Patient Education in a Timely Manner

The typical hospital EMR utilizes standardized tools, such as tasks, reminders, and education modules to allow you to provide patients with education on various topics. Before you begin, you should work with subject matter experts to determine which tool works best within your EMR system and users' workflows to display educational materials for patients.

Takeda has developed *Navigating Population Health Management: Primary Immunodeficiency (PI)*—a population health toolkit designed to help health systems with the identification and management of PI. This kit includes patient education materials that can be duplicated within your EMR.

Contact your Takeda representative to obtain a copy of *Navigating Population Health Management: Primary Immunodeficiency (PI)*.

Steps

- Review the patient education materials in the *Navigating Population Health Management: Primary Immunodeficiency (PI)* toolkit with your clinical experts and determine which subjects or topics you will include as a part of your EMR PI education
 - Consider selecting components of the *Navigating Population Health Management: Primary Immunodeficiency (PI)* toolkit and adding them to your EMR system
 - You do not have to include all information for every patient
 - Instead, you can choose to display disease-specific information based on a patient's individual PI diagnosis, information based on a patient's age, and other additional information as you see fit
-
- If your EMR allows you to create educational content that is organized by hierarchy, create these records or files to fit the content you reviewed with your clinicians
 - The most general or higher level portions of the content will contain subtopics and education points
 - *Skip this step if your EMR doesn't allow this*
-
- Create records or files that contain the text that will be shown in your EMR
-
- Configure your EMR logic or rules so that this newly created educational material appears for clinicians when a patient is diagnosed with PI

Scenario 3: Providing Patients With Additional Support

Objective

To implement the EMR to automatically add standardized content for the MyIgSource patient support program available at MyIgSource.com into a clinical or visit summary that is given to the patient at the end of their visit or upon discharge. The patient will then be able to use this printed information to learn more about MyIgSource and the program's resources.

These resources will be provided to patients who have recently been documented by an ICD-10 code for PI in their electronic chart. The patient may have recently been diagnosed with PI, was in the office for a recent visit, or visited the office for a chronic problem.



Hypothetical Situation

- Dr. Smith and her colleagues provide patients with excellent care
- However, patient support programs, such as MyIgSource, can be excellent resources for patients and provide additional education on various topics, as well as give a sense of community for those living with a rare disease
- Dr. Smith wants to make sure that patients with PI across the healthcare network are made aware of these programs by providing them with information that they can take home and use to research and connect with patient support programs

Did
You
Know?

Patients with PI may be unaware of support programs that offer:

- Educational resources
- Patient advocates

MyIgSource is an educational resource where patients **can learn more about PI** and **connect with an individual who is living with PI** or has a loved one with PI

MyIgSource is **open to all patients**, regardless of treatment

Solution Blueprint: Utilizing Available Educational Resources for Patients

The typical hospital EMR utilizes different tools to allow for different documents and forms to be printed based on a patient's diagnosis. Your EMR or health system may refer to this printed document as a clinical or visit summary, as well as patient or discharge instructions.

Contact your Takeda representative to obtain outreach content for MylgSource patient support program created for the EMR Partnership Program.

Steps

- Locate the file or record in your EMR that determines the documents or forms that will be printed at the end of a visit or upon discharge, and then given to a patient
- **If the document/form exists in one file or record:** Replicate the existing file or record and add the patient support program information in the appropriate location
- **If the document/form exists in multiple files or records (such as a clinical summary AND discharge summary):** Create a section for the patient support program outreach content and add it to the master file or record for clinical or visit summary

Configure your EMR's rules, logic, or clinical support tools so that...

- **If the document/form exists in one file or record:** The additional content will only print for patients with PI
- **If the document/form exists in multiple files or records (such as a clinical summary AND discharge summary):** The additional sections will only print for patients with PI

Scenario 4: Ensuring Adherence to Ig Use Protocols

Objective

To identify patients with PI who have been recently prescribed an IVIg medication in the inpatient setting that may not adhere to the medication protocol (the ratio of a patient's body weight to medication dose is greater than 2:1 [kilograms to grams]) by developing a report generated from the EMR that can be delivered and used periodically.

This scenario is only intended for use by organizations that have protocols for IVIg use in place. This scenario does not endorse or suggest that your organization use any specific protocols or guidelines.



Hypothetical Situation

- In the inpatient setting, IVIg is used to treat a number of different diseases and conditions, including PI
- Clinicians often used different guidelines or protocols to determine how much IVIg to use when treating patients with PI
 - As a result, some IVIg doses were too high. To improve patient care and help clinicians be more conservative with their use of IVIg, hospitals have instituted standard dosing protocols
- While the use of IVIg dosing protocols may vary across different hospitals, Dr. Smith's institution decided that doses should not exceed 1 g of IVIg for every kg of patient body weight
- Dr. Smith believes that some of her colleagues have not been adhering to protocol and wants to use the EMR in order to find administrations of IVIg that do not follow protocol

Did
You
Know?

Over 1/3 of organizations reported that inappropriate Ig use was a top gap in patient care in 2016.¹³

≥50% of organizations said managing utilization is a top management priority.¹³

Less than **50%** of organizations had a program in place to monitor Ig use in 2016.¹³

Solution Blueprint: Conduct a Medication Adherence Search to Make Sure Protocols Are Being Met

The typical hospital EMR allows you to search for medication orders that meet certain criteria. Locate the reporting or search tool that allows you to search orders or medications within your EMR.

Steps	What to search
1. Limit the time period you are searching to one year in the past	For example, if today is January 30, 2020, you will want to search January 30, 2019 through January 30, 2020.
2. Include the IVIg medications	<p>List the desired IVIg medications you wish to include in this search.</p> <p>Some EMR search tools allow you to use “AND” or “OR” logic</p> <ul style="list-style-type: none"> ■ If your EMR allows this, use “OR” logic for this parameter ■ If your EMR does not allow this type of logic, you may also search each medication listed separately for each diagnosis you wish to search in the next step
3. Include patients with an existing PI diagnosis	<p>To include patients already diagnosed with PI, set your search to find patients that have been diagnosed with ICD-10 codes that may be used for PI, including¹²:</p> <p>D15, D46.9, D70.0, D70.8, D71, D72, D76.1, D80.0, D80.1, D80.2, D80.3, D80.4, D80.5, D80.6, D80.7, D80.8, D80.9, D81.0, D81.1, D81.2, D81.3, D81.4, D81.5, D81.6, D81.7, D81.89, D81.9, D82.0, D82.1, D82.2, D82.3, D82.4, D82.8, D82.9, D83.0, D83.1, D83.2, D83.8, D83.9, D84.1, D84.9, D89.9, G11.3</p> <p>Some EMR search tools allow you to use “AND” or “OR” logic</p> <ul style="list-style-type: none"> ■ If your EMR allows this, use “OR” logic for this parameter ■ If your EMR does not allow this type of logic, you may also search each existing diagnosis listed above separately for each medication you wish to search in previous step
4. Limit the IVIg medications to those that have been administered	<p>The typical hospital EMR has parameters or criteria that allow your search to filter results</p> <ul style="list-style-type: none"> ■ Configure this criterion to only include orders or prescriptions that have been acted upon ■ Your system may use a status of “completed” or “administered” <ul style="list-style-type: none"> - Example: orders for IVIg that have been given to the patient, not orders that have only been written, canceled, or are pending
5. Configure protocol adherence calculation if needed	<p>Your reporting tool must be able to determine if patient-specific IVIg administrations are outside of a certain range</p> <ul style="list-style-type: none"> ■ Some systems allow you to simply highlight values based on mathematical equations ■ Others may require additional customization, including the creation of special data sets or columns, in order to achieve this <p>For example: if your organization’s protocols call for 0.5 g of IVIg for every kg of body weight, a 60-kg patient should receive 30 g of IVIg. However, a 70-kg patient should receive a 35-g dose. Therefore, this column’s calculation should display the same number for both patients. If these were your organization’s guidelines, a column that calculated [MEDICATION DOSE/PATIENT WEIGHT] could be used. In this example, a value of 0.5 g would be the optimal value.</p> <p><i>Note: The protocol above is meant as an example only.</i></p>
6. Configure report appearance	If your EMR allows, configure your report to highlight administrations that may fall outside of the acceptable dose range.

Scenario 5: Ensuring Prescriptions Are Filled In-Network

Objective

To identify patients who have an ICD-10 diagnosis for PI in their electronic chart, who have been recently prescribed an IVIg or SCIg medication, which may not have been filled, by developing a report generated from the EMR that can be delivered and used periodically among private office practitioners and hospital network medical professionals.



Hypothetical Situation

- Dr. Smith has noticed that the specialty pharmacy, part of the hospital's network, has filled fewer prescriptions for SCIg medications lately
- This presents a problem for the hospital network, as it made a large investment to build its own specialty pharmacy
- Dr. Smith suspects that patients may be filling SCIg prescriptions written by clinicians in her network at other specialty pharmacies instead of the in-network pharmacy
 - Before Dr. Smith can bring this issue to her colleagues, she needs to confirm whether her suspicions are correct
 - To do this, she wants to use the EMR to determine whether the in-network pharmacy is filling fewer SCIg prescriptions than expected

Did
You
Know?

20% of prescriptions go unfilled¹⁴

Health networks lose potential revenue when patients fill prescriptions elsewhere¹⁵

The estimated average cost of Ig therapy is **\$30,000** a year¹⁶

Identifying prescriptions filled out-of-network could help you find ways **to ensure patient care is properly coordinated** and that your financial health is sustainable

Solution Blueprint: Conduct a Search to Determine Whether Prescriptions Are Being Filled In-Network

The typical hospital EMR allows you to search for orders or actions that meet certain criteria. Locate the reporting or search tool that allows you to search orders or medications within your EMR.

Steps	What to search
1. Limit the time period you are searching to one month in the past	For example, if today is January 30, 2020, you will want to search January 1, 2020 through January 30, 2020.
2. Limit the prescriptions to those that have not been filled	<p>The typical hospital EMR has parameters or criteria that allow your search to filter results</p> <ul style="list-style-type: none"> ■ Set your search to find those to include only orders or prescribed medications that are still pending or incomplete ■ Your system may use a status of “completed” to signify a completed order or filled prescription
3. Include the IVIg and/or SCIg medications	<p>List the desired IVIg and/or SCIg medications you wish to include in this search.</p> <p>Some EMR search tools allow you to use “AND” or “OR” logic</p> <ul style="list-style-type: none"> ■ If your EMR allows this, use “OR” logic for this parameter ■ If your EMR does not allow this type of logic, you may also search each medication listed separately for each diagnosis you wish to search in the next step
4. Include patients with an existing PI diagnosis	<p>To include patients already diagnosed with PI, set your search to find patients that have been diagnosed with ICD-10 codes that may be used for PI, including¹²:</p> <p>D15, D46.9, D70.0, D70.8, D71, D72, D76.1, D80.0, D80.1, D80.2, D80.3, D80.4, D80.5, D80.6, D80.7, D80.8, D80.9, D81.0, D81.1, D81.2, D81.3, D81.4, D81.5, D81.6, D81.7, D81.89, D81.9, D82.0, D82.1, D82.2, D82.3, D82.4, D82.8, D82.9, D83.0, D83.1, D83.2, D83.8, D83.9, D84.1, D84.9, D89.9, G11.3</p> <p>Some EMR search tools allow you to use “AND” or “OR” logic</p> <ul style="list-style-type: none"> ■ If your EMR allows this, use “OR” logic for this parameter ■ If your EMR does not allow this type of logic, you may also search each existing diagnosis listed above separately for each medication you wish to search in the previous step

Scenario 6: Ensuring Referrals Stay In-Network

Objective

To identify referrals to an immunologist for a patient who has an ICD-10 diagnosis for PI in their electronic chart, who may not have scheduled or completed a visit, by developing a report generated from the EMR that can be delivered and used periodically.



Hypothetical Situation

- When a patient is newly diagnosed or may present with symptoms of PI, clinicians will often refer them to an immunology specialist who can provide them with specialized care
- Dr. Smith has been working with the hospital's immunologist, Dr. Reed, to coordinate her patients' care
 - However, not all of Dr. Smith's patients schedule an appointment with Dr. Reed
 - Dr. Smith and Dr. Reed aren't sure why some patients don't schedule their appointments, but want to follow up with them to make sure they receive the needed care
 - To do this, they want to use the EMR to find patients with PI who have been referred to an immunologist, but have not scheduled an appointment

Did
You
Know?

An estimated **24%** to **30%** of referrals are scheduled out-of-network¹⁷

Solution Blueprint: Conduct a Search to Determine If Referrals Are Being Filled In-Network or Out-of-Network

The typical hospital EMR allows you to search for orders or actions that meet certain criteria. Locate the reporting tool that allows you to search orders or referrals within your EMR.

Steps	What to search
1. Limit the time period you are searching to one month in the past	For example, if today is January 30, 2020, you will want to search January 1, 2020 through January 30, 2020.
2. Limit the orders or referrals included in your search	<p>The typical hospital EMR has parameters or criteria that allow your search to filter results. If your EMR allows your organization to use different orders or referrals, list the desired ones.</p> <p>Some EMR search tools allow you to use “AND” or “OR” logic</p> <ul style="list-style-type: none"> ■ If your EMR allows this, use “OR” logic for this parameter ■ If your EMR does not allow this type of logic, you may also search each order or referral listed separately for each diagnosis you wish to search in the next step
3. Include patients with an existing PI diagnosis	<p>To include patients already diagnosed with PI, set your search to find patients that have been diagnosed with ICD-10 codes that may be used for PI, including¹²:</p> <p>D15, D46.9, D70.0, D70.8, D71, D72, D76.1, D80.0, D80.1, D80.2, D80.3, D80.4, D80.5, D80.6, D80.7, D80.8, D80.9, D81.0, D81.1, D81.2, D81.3, D81.4, D81.5, D81.6, D81.7, D81.89, D81.9, D82.0, D82.1, D82.2, D82.3, D82.4, D82.8, D82.9, D83.0, D83.1, D83.2, D83.8, D83.9, D84.1, D84.9, D89.9, G11.3</p> <p>Some EMR search tools allow you to use “AND” or “OR” logic</p> <ul style="list-style-type: none"> ■ If your EMR allows this, use “OR” logic for this parameter ■ If your EMR does not allow this type of logic, you may also search each existing diagnosis listed above separately for each order or referral in the previous step
4. Limit the referrals to those that have not been completed	<p>The typical hospital EMR has parameters or criteria that allow your search to filter results. Set your search to only include orders or referrals that are incomplete. Your system may use a status of “completed” to signify a completed order or referral.</p>

Scenario 7: Providing Best-In-Class Care

Objective

To ensure assessment, charting, or documentation tasks are standardized and specific to patients with PI will be automatically added to a clinician's workflow, post initial diagnosis, during an office visit, or at follow-up appointments for a chronic condition in their electronic chart. These tasks will appear in addition to, not in place of, the standard assessment, charting, or documentation tasks.



Hypothetical Situation

- Patients with PI need special care, and even though there are specialists who can provide the best possible care, every clinician should be equipped to provide better care for these patients
- The typical hospital EMR allows for different tasks—recording and collecting information—based on a patient's diagnosis or condition when a clinician is completing their assessment or charting workflow
 - Whether that occurs during a routine check-up or visit to the emergency room
- Dr. Smith and Dr. Reed agree that standardized tasks for patients with PI should be added to the EMR

Did
You
Know?

PIs are chronic and patients require special attention from providers to ensure they receive adequate care¹⁸

Equipping providers to treat patients with PI will lead to better outcomes¹⁸

Solution Blueprint: Customizing the Delivery of Patient Care in an EMR System

The typical hospital EMR allows you to utilize existing tools to create standardized activities, checklists, and charting or documentation tasks.

Steps

Consult your IT department and workflow subject matter experts to determine the best tool to use for this solution

- Your EMR system may offer multiple tools, such as flowsheets, nursing assessments, charting tasks, or other specialized activities
- It is important to design your system configuration around the tools already utilized by your providers to ensure there is no disruption to this workflow

Review the content below with your clinical experts. Determine if any changes are needed and then edit this to create standardized content that will appear for clinicians in your EMR.

Topics

What to Document

Use the topics below for patients with PI during all visits

Assessing Current Health¹⁹

Document the patient's current health:

- Temperature
- Weight
- Heart rate
- Hydration status
- Changes in health since last visit
- Illnesses since last visit

Documenting Current Care Plan^{19,20}

Document in the EMR whether the patient has adhered to the prescribed treatment regimen, including *premedications, hydration, routine medications, etc.*

If the patient is currently on or starting medication, document:

- Product
- Dose
- Frequency of administration
- Rate of infusion, if applicable

Continued on next page

Solution Blueprint: Customizing the Delivery of Patient Care in an EMR System (continued)

Topics	What to Document
Use the topics below for patients with PI during all visits	
Assessing Quality of Life²¹	<p>Assess the patient's quality of life using the following questions:</p> <ul style="list-style-type: none"> ■ <i>How satisfied or dissatisfied are you with the ability of the medication to prevent or treat your condition?</i> ■ <i>How satisfied or dissatisfied are you with the way the medication relieves your symptoms?</i> ■ <i>How satisfied or dissatisfied are you with the amount of time it takes the medication to start working?</i> ■ <i>Is your experience optimal or are there issues you would like to discuss?</i> ■ <i>How easy or difficult is it to plan when you will use the medication each time?</i> ■ <i>How convenient or inconvenient is it to take the medication as instructed?</i> ■ <i>Overall, how confident are you that taking this medication is a good thing for you?</i> ■ <i>How certain are you that the good things about your medication outweigh the bad things?</i> ■ <i>Taking all things into account, how satisfied or dissatisfied are you with this medication?</i>
	<p>Assessing Adherence to Care Plan^{19,20}</p> <p>Document in the EMR whether the patient has adhered to the prescribed treatment regimen, including <i>premedications, hydration, routine medications, etc.</i></p>
Use the topics below for patients with PI during an Ig therapy infusion (in addition to topics above)	
Pre-infusion Assessment (all Ig therapy)^{19,a}	<p>Document the patient's current IgG trough level</p> <p>Document whether the patient has experienced any of the following after an infusion with their current product: <i>pyogenic reactions, allergic reactions, anaphylactoid reactions, chills/rigors, headache, migraine, flu-like symptoms, urticaria (hives), vasomotor symptoms (hypertension, flushing, hot flashes), nausea/vomiting, back pain/hip pain/arthritis/myalgias, local itching, redness, burning, swelling, rash, discomfort</i></p>
	<p>Confirm and document:</p> <ul style="list-style-type: none"> ■ Correct product for patient ■ Correct dose of product prepared ■ Product lot number documented ■ Product protective seals are intact ■ Product is at room temperature ■ If pre-medications are needed ■ If there is a need for localized anesthesia ■ Emergency services are available if needed

Continued on next page

Solution Blueprint: Customizing the Delivery of Patient Care in an EMR System (continued)

Topics	What to Document
Intra-infusion Assessment (all Ig therapy)^{19,a}	<p>Assess the following every 15 to 30 minutes during the infusion:</p> <ul style="list-style-type: none"> ■ Vital signs ■ Rate of infusion ■ Patient comfort/complaints <p>Assess whether the patient has signs of the following every 15 to 30 minutes during the infusion: <i>pyogenic reactions, allergic reactions, anaphylactoid reactions, chills/rigors, headache, migraine, flu-like symptoms, urticaria (hives), vasomotor symptoms (hypertension, flushing, hot flashes), nausea/vomiting, back pain/hip pain/arthralgias/myalgias, local itching, redness, burning, swelling, rash, discomfort</i></p>
Post-infusion Assessment (all Ig therapy)^{19,a}	<p>Document the time required to complete infusion</p> <p>Document whether the patient exhibits symptoms of: <i>pyogenic reactions, allergic reactions, anaphylactoid reactions, chills/rigors, headache, migraine, flu-like symptoms, urticaria (hives), vasomotor symptoms (hypertension, flushing, hot flashes), nausea/vomiting, back pain/hip pain/arthralgias/myalgias, local itching, redness, burning, swelling, rash, discomfort</i></p> <p>Recommendations for next infusion (enter pre-medications or other notes)</p> <p>Confirm and document that the patient is aware of their:</p> <ul style="list-style-type: none"> ■ Next infusion date ■ Responsibilities regarding the next infusion
SCIg Post-infusion Assessment (SCIg only)^{19,21,a} (Use in addition to Post-infusion Assessment above)	<p>Document any patient teaching interventions and the patient's ability to administer their own infusions</p>

Configure your workflow or clinical decision support rules or logic to have the content tool you have created display during a clinician's assessment, documentation, information collection, or charting for patients diagnosed with PI.

^a Please notify the Manufacturer's Customer Service/Medical Affairs of any allegation of deficiencies related to identity, integrity, quality, durability, reliability, safety, effectiveness or performance for their product.



References: **1.** Picard C, Gaspar HB, Al-Herz W, et al. International Union of Immunological Societies: 2017 Primary Immunodeficiency Diseases Committee report on inborn errors of immunity. *J Clin Immunol*. 2018;38(1):96-128. **2.** Immune Deficiency Foundation. 2013 IDF National Immunoglobulin Treatment Survey. https://www.primaryimmune.org/sites/default/files/2013_IDF_National_Immunoglobulin_Treatment_Survey.pdf. Accessed January 9, 2020. **3.** Bonilla FA, Bernstein IL, Khan DA, et al. Practice parameter for the diagnosis and management of primary immunodeficiency. *Ann Allergy Asthma Immunol*. 2005;94(5):S1-S63. **4.** Modell F, Puente D, Modell V. From genotype to phenotype: further studies measuring the impact of a physician education and public awareness campaign on early diagnosis and management of primary immunodeficiencies. *Immunol Res*. 2009;44(1-3):132-149. **5.** Immune Deficiency Foundation. Patient & family handbook for primary immunodeficiency diseases. <https://primaryimmune.org/wp-content/uploads/2016/03/IDF-Patient-Family-Handbook-5th-Edition-2015-Reprint-Web.pdf>. Accessed January 9, 2020. **6.** Immune Deficiency Foundation. Primary immunodeficiency diseases in America: 2007: the third national survey of patients. <https://primaryimmune.org/wp-content/uploads/2011/04/Primary-Immunodeficiency-Diseases-in-America-2007-The-Third-National-Survey-of-Patients.pdf>. Accessed January 9, 2020. **7.** Resnick ES, Bhatt P, Sidi P, Cunningham-Rudles C. Examining the use of ICD-9 diagnosis codes for primary immune deficiency diseases in New York State. *J Clin Immunol*. 2013;33(1):40-48. **8.** Jeffrey Modell Foundation. Ten warning signs of primary immunodeficiency. <http://downloads.info4pi.org/pdfs/10-Warning-Signs---Generic-Text--2-.pdf>. Accessed January 9, 2020. **9.** Orange JS, Seeborg FO, Boyle M, Scalchunes C, Hernandez-Trupillo V. Family physician perspectives on primary immunodeficiency disease. *Front Med*. 2016;3:12. **10.** Centers for Medicare & Medicaid Services. Medicare shared savings program quality measure benchmarks for the 2016 and 2017 reporting years. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharesavingsprogram/Downloads/MSSP-QM-Benchmarks-2016.pdf>. Accessed January 9, 2020. **11.** Modell V, Orange JS, Quinn J, Modell F. Global report on primary immunodeficiencies: 2018 update from the Jeffrey Modell Centers Network on disease classification, regional trends, treatment modalities, and physician reported outcomes. *Immunol Res*. 2018;66(3):367-380. **12.** Centers for Medicare & Medicaid Services. ICD-10-CM Tabular List of Diseases and Injuries. <https://www.cms.gov/Medicare/Coding/ICD10/2020-ICD-10-CM>. Accessed February 21, 2020. **13.** Data on file (2016 Baxalta IDN Benchmark/Equity Assessment; October 30, 2017). **14.** Becker TW, Ade S. Capturing new sources of revenue and savings with a hospital-owned outpatient pharmacy: a white paper providing five best practices. https://cdn2.hubspot.net/hubfs/3938051/01026_CPS_Outpatient_White_Paper.pdf. Accessed January 9, 2020. **15.** Barlas S. Specialty pharmacy networks for hospitals in the offing: absence of onsite access to specialty pharmaceuticals has care and financial implications. *PT*. 2014;39(2):123-143. **16.** Modell V, Quinn J, Orange J, Notarangelo JD, Modell F. Primary immunodeficiencies worldwide: an updated overview from the Jeffrey Modell Centers Global Network. *Immunol Res*. 2016;64(3):736-753. **17.** Rappleye E. Referral networks, stopping leakage and technology investments: 5 top revenue generation strategies for CFOs. Becker's Hospital CFO Report website. <http://www.beckershospitalreview.com/finance/referral-networks-stopping-leakage-and-technology-investments-5-top-revenue-generation-strategies-for-cfos.html>. Accessed January 9, 2020. **18.** Ballow M, Notarangelo L, Grimbacher B, et al. Immunodeficiencies. *Clin Exp Immunol*. 2009;158(suppl 1):14-22. **19.** Immune Deficiency Foundation. IDF guide for nurses: Immunoglobulin therapy for primary immunodeficiency diseases. 4th ed. <https://primaryimmune.org/sites/default/files/publications/IDF-Guide-for-Nurses-4th-Edition.pdf>. Accessed January 9, 2020. **20.** Kirmse J, Schleis T. IgNS Immunoglobulin Therapy Standards of Practice, 2nd Edition. Woodland Hills, CA: Immunoglobulin National Society; 2018. **21.** Atkinson MJ, Sinha A, Hass SL, et al. Validation of a general measure of treatment satisfaction, the Treatment Satisfaction Questionnaire for Medication (TSQM) using a national panel study of chronic disease. *Health Qual Life Outcomes*. 2004;2:12.