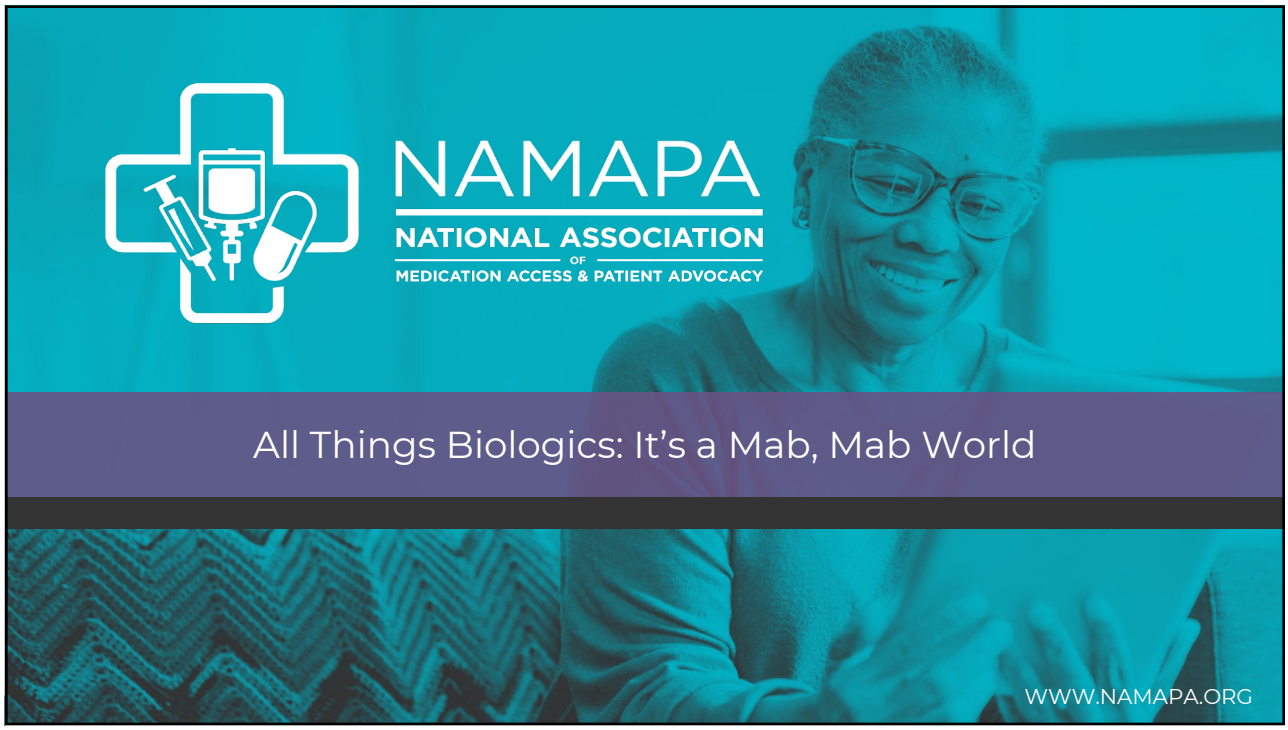

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Disclosures

- No Financial Relationships

Other Board/Committee Involvement:

- Advisory Council Member, Customer Experience Program - George Washington School of Business
- Executive Committee Member, ACMA (PACS Certification)
- Board Member, The Dlabal Foundation
- Standards Committee Member, NICA
- Financial Navigation Committee, ACCC

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2

Disclaimer - Buckle Up!

Agenda:

- Overview of Biologics Access
- Biologics Operations
- Payer Impact on Biologics
- Financial Advocacy

This is a marathon, but we will get through it together!

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Elizabeth Johnson

Licensed Practical Nurse
Certified Professional Coder
Prior Authorization Certified Specialist
Board Certified Patient Advocate
(LPN, CPC, PACS, BCPA)

CEO, MedicoCX
President & Co-founder of NAMAPA
Co-CEO, Healthcare Advocate Summit

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Who and What is NAMAPA?

The National Association of Medication Access and Patient Advocacy is a non-profit (501c3) organization dedicated to helping
healthcare advocates feel confident in their medication access roles.

Healthcare Advocates are the individuals who work between the provider and the patient and encompass many different roles, descriptions, and parts of the complicated process.

This is a different take on patient advocacy as we focus our education and resources around healthcare workers.

NAMAPA is non-therapeutic specific to prevent recreating the wheel - the process is the process no matter the disease state, medication, payer, state, etc.

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Everyone is short on time, staff, and resources.

Change sucks.

"That's not my job…"

"He/she doesn't do their part…"

Burnout is real, so let's think smarter not harder and use our community to lean in and on!

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Working with Biologics

He was, and still is, perfectly fine!

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What's the Big Deal?

Biologics are a **HOT** topic right now, not just in respiratory but across many specialties: oncology, rheumatology, neurology, GI, retina, dermatology…

Biosimilars are here and more are coming and will offer even more choices for patients.

They cost A LOT and require special shipping and storage. One missed vial/syringe can take many future injections or administrations to cover the lost cost.

High cost + low margin = NO (or little) room for error

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So Why Bother?

THE PATIENTS!!!!!

Everything we do is for them!

- Physicians decide the most clinically appropriate treatment
- Race to get patients on therapy
- Provide cost savings (copay cards, grants, etc.)
- Continuity of care

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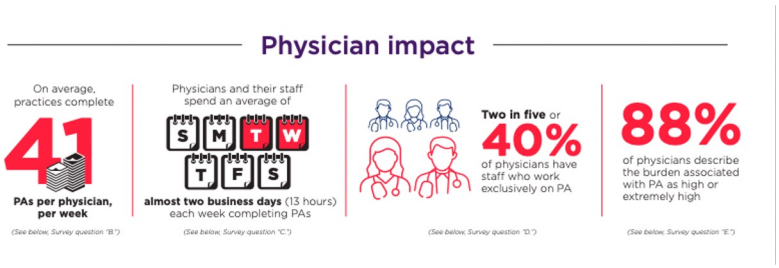
Another Reason…

- Your time is valuable!
- According to the 2021 AMA Physician survey on Prior Auth:



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Current Hiccups

- TIME
- SPECIALTY PHARMACIES
- Portal Fatigue
- COVID
- Policy changes
- Utilization management changes
- Phone/fax number changes
- New Medications

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Top 5 Questions

1. How long does it take to get a prior authorization done?
2. How do I know it's been approved?
3. How do I know medication has been shipped?
4. Who is checking claims?
5. Who can help me?

Honorable Mentions:
- Won't patients have to pay more?
- Do I really need dedicated staff to biologics?

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Why DOES it take so long?

- Medical benefit vs pharmacy benefit
- Different types of pre-service review
- Various methods of submitting requests for pre-service review
- Subject to payer review times (some can be instant and some up to 15 days)

Basically, we are at the mercy of the payers…

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Types of Insurance

- **Self or Broker** - You can purchase insurance coverage directly from the company or have an insurance broker help you purchase after exploring options.
- **Employers** - Offered to qualified employees, the plan can be customized as far as offerings, coverage, and any additional support from the employer. Options presented to employees are chosen based on a multitude of factors.
- **Marketplace** - The Affordable Care Act (ACA) was passed in 2010 and changed the under vs uninsured parameters. Patients can search plans and utilize tax credits (if eligible) to cover premiums.
- **Government** -
  - Medicare: 65+ individuals or other qualified patients
  - Medicaid: State issued
  - Tricare: Military
- **Health Sharing** - Typically faith based but new programs are emerging. All members pay into the plan and services are covered by the group.

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Medical vs Pharmacy Benefits

- Medical or "Major Medical"
  - Covers physician/provider services
  - Covers medications given by a provider or facility
  - Cost is associated with plan deductible, co-pay, or co-insurance amounts
- Pharmacy
  - Pharmacy benefit deductible is separate
  - Part D for Medicare beneficiaries
  - Can be subject to co-payment, co-insurance or most frequently follows a tier system
  - Retail vs specialty pharmacy
  - Mail order, 90 day vs 30 day dispense

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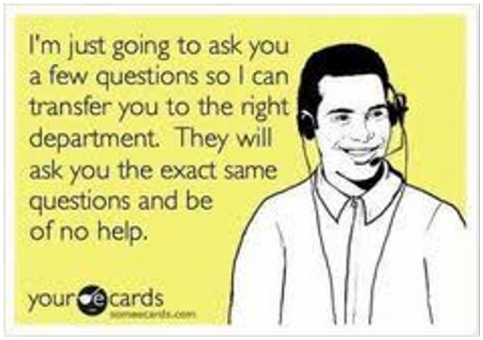
Pre-Service Review

It's not *just* Prior Authorization…

First step, is a benefits investigation



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Benefit Investigation

YOU ARE ONLY AS GOOD AS THE REP YOU GET ON THE PHONE

YOU ARE ONLY AS GOOD AS THE DATA DISPLAYED ON THE PORTAL OR WEBSITE AT THAT TIME

DOCUMENT, DOCUMENT, DOCUMENT!

- Rep name
- Date and time of call
- Reference number (sometimes this is date and time)
- Network
- Deductible (self, family, max, current utilization)
- Co-pay
- Co-Insurance
- Preferred admin code
- J code specific coverage
- Utilization management requirements

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Utilization Management

- Prior Authorization - **Medical**: some payer portals allow for immediate determinations but with medical reviewers still physically reading clinical notes, some payers ask for up to 15 days. Seasonally, it can be even longer.
- Prior Authorization - **Pharmacy**: ePA has changed the speed at which determinations are rendered. Some come back instantly and others take 24-72 hours to review
- Pre-Determination: typically must be a written request (fax or mailed) and select payers can allow up to 45 days for review. Many times these are voluntary, best practice is complete this process voluntary or not.
- Advanced Benefit Determination: Federal plans, must be submitted before services are rendered and are voluntary. Again, best practice is to submit!
- Medical Necessity Review: Can happen pre or post services. Pre is voluntary, post service can delay claim adjudication and many times medical records are requested.

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Need to Know BEFORE Starting:

- Preferred method of acquisition:
  - Buy and bill
  - Specialty pharmacy
- Medication:
  - Route of administration
  - Site of care
- Manufacturer help:
  - Hub forms
  - Benefit investigation
  - Copay assistance
- Insurance: buy and bill eligible or carve out to SP, step edits, formulary, request type for coverage
  - Voluntary vs Required
  - Pre or post service
  - Carve out

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Specialty Pharmacy

- Organization and tracking of patients
- Refill times
- Patient/Office coordination
- Call with multiple patients at one time
- Warm transfers vs cold
- Sadly, you're not alone in the frustrations

Tech Solutions:
- RxLightning

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Buy and Bill

- You buy it, you bill it when administered
- Additional revenue line
- Cash flow cycle is critical to know
- Requires same level of detail as any other biologics process
  - IF YOU'RE FOLLOWING BEST PRACTICES ALREADY
- It's not going away, just getting harder

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Best Practices

Complete all necessary paperwork

- Order/Prescription
- Manufacturer/hub forms
- Referral information
- Insurance required information

Provide thorough documentation

- Clinical history
- Labs, radiology or other procedures
- Medication history

Educate Patient on the process and their responsibilities

- Copay or other financial assistance
- Answering when 800 numbers call (hubs, pharmacies, insurance…)

Be prepared for questions!

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There isn't an Easy Button

- Everything takes time – just make sure enough time is allowed
- Mistakes are easy to make with coding – know the codes and code types
- Mistakes can be fixed but be aware (see #1)
- If you are unsure, ask! It is more helpful to ask how to submit something than to keep submitting it incorrectly
- Be aware of payer policies and their medical criteria
- There is an ICD 10 code for everything, but only a select few that a medication is approved for
- Benefit Investigations are important, use the manufacturers AND do your own!
- Sometimes an appeal isn't required, re-check which benefit is needed to acquire the medication
- Hubs can be your best friend
- Network! Connect! Someone somewhere has experienced a similar situation, ask how/what they did and the outcome

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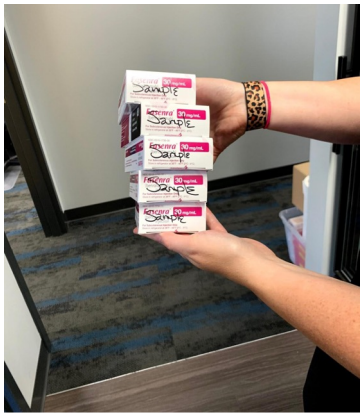
Ways to Make it a Little Harder



Please don't label your purchased products as samples...

Also, please don't swap samples with any other product or bill for samples.

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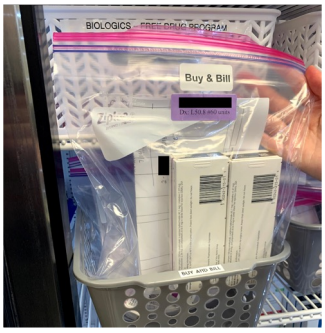
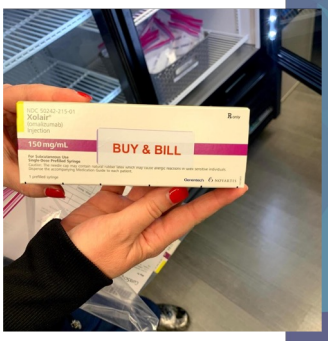
Ways to Make it a Little Easier





Storage and Inventory is essential, not just for organization but for patient adherence.

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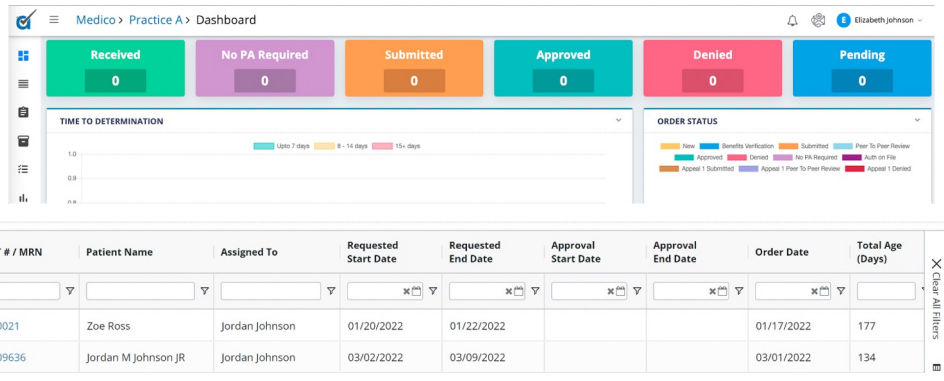
Patient Name	DOB	Effective	Expiration	BB/SP	Medication	Insurance	DX	Sig
		8/10/2021	8/9/2022	SP	Dupixent	BCBS	J33.9	300mg q2wks
		8/9/2021	8/9/2022	SP	Dupixent	BCBS	J33.9	300mg q2wks
		2/10/2022	8/10/2022	**BB**	Xolair	UHC	L50.1	300mg q4wks
			8/16/2022	SP	Dupixent	BCBS	L20.9	300mg q2wks
		2/21/2022	8/21/2022	SP	Dupixent	Aetna	J33.9	300mg q 2wks
		8/24/2021	8/23/2022	SP	Fasenra	Cigna	J45.50	30mg q8wks
		8/24/2021	8/24/2022	SP	Dupixent	Cigna	J33.9	300mg q2wks
		8/27/2021	8/26/2022	**BB**	Xolair	Aetna	L50.1	300mg q4wks



PT # / MRN	Patient Name	Assigned To	Requested Start Date	Requested End Date	Approval Start Date	Approval End Date	Order Date	Total Age (Days)
10021	Zoe Ross	Jordan Johnson	01/20/2022	01/22/2022			01/17/2022	177
709636	Jordan M Johnson JR	Jordan Johnson	03/02/2022	03/09/2022			03/01/2022	134

Clear All Filters

Workflow tools and tech solutions can be a life saver!

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In a Perfect World

- Enrollment forms are completed via portal or faxed to the manufacturer; the patient is instructed to apply for a copay card (commercial insurance)
- Evaluate payer policy and medical criteria of the patient to make initial decision to pursue medical benefit coverage (vs pharmacy)
- Benefit investigation comes back from manufacturer
- PA is submitted and documented in EHR system, then marked for follow up based on plans review time
- Determination comes back and medication is acquired for appropriate benefit (purchased from distributor for buy and bill or ordered from specialty pharmacy)
- Patient is scheduled for injection administration
- Eligibility is checked 2 business days before appointment
- Patient is administered medication and billed for appropriate services
- Claim is adjudicated and copay assistance processed, if applicable

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Crash Course: Medicare

BE AWARE:

To reduce premiums for seniors, there are two different options for Plan F and Plan G out there - High Deductible

- Plan HDF
- Plan HDG

2022 deductible amount: $2,490.00

Medigap Supplement Plan C

- Has been discontinued if you were eligible after 2020
- Confused with Medicare Advantage ***Part C***

**Plan F, High Deductible Plan F & Plan C are ONLY available to those who were considered Medicare-eligible prior to 2020

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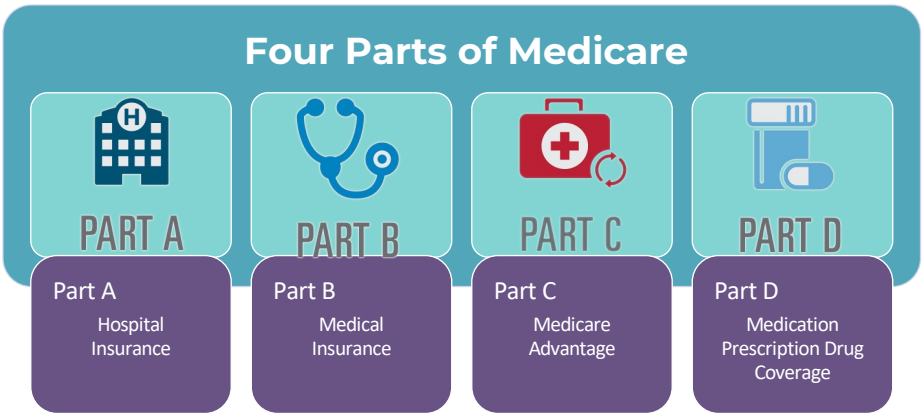
Medicare Coverage Basics



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Part B: Medical Insurance

- Covers
  - INFUSIONS – Chemotherapy, Immunotherapy, other Biologics
  - Outpatient Medications – some oral chemo, nebulizers, immunosuppressants
  - Outpatient care
  - Doctor's Services
  - Preventative care
  - Home health care – intermittent and part-time
  - Durable Medical Equipment
  - Ambulance Services
- Part B Yearly Deductible = $233 for 2022
- Part B Coinsurance = 20% after deductible is met

PART B

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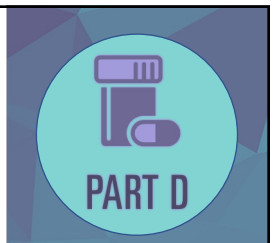
Part D: Prescription Drug

- Run by private insurance companies
- Many Medicare Advantage plans include Part D
- There is no "pre-existing condition clause"
- Plans have different formularies, cost structures and preferred pharmacies

Individuals' plans should be reviewed each year during Open Enrollment



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Part D: Prescription Drug

Tiering Example

Drug Tier	What It Means
Tier 1	**Preferred Generic** – Commonly prescribed generic drugs
Tier 2	**Generic** - More costly generic drugs
Tier 3	**Preferred Brand** – Lower priced brand name drugs that do not have a generic equivalent
Tier 4	**Nonpreferred Drug** – Higher priced brand name and generic drugs not in a preferred tier
Tier 5	**Specialty** – Most expensive drugs. Usually used to treat complex conditions

Every Plan is different. The right plan is determined by the beneficiary's prescriptions and pharmacy preference.

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Part C: Medicare Advantage

- Plans offered by private insurance companies (HMO's, PPO's, PFFS)
- Use doctors and hospitals in plan's network
- Combines Parts A & B and +/- Part D
- Some offer additional benefits not covered under Original Medicare
  - Dental/Hearing/Vision
    - Benefits are limited
    - Can pay for a higher premium for additional benefits through the plan
    - Or could purchase separate plans, especially dental
  - Wellness programs
- Premiums, copays, coinsurance and deductibles vary by plan
- Still pay Part B premium - deducted from SSA
- LIMIT ON OUT OF POCKET COSTS!!!

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Original Medicare vs. Medicare Advantage

Original Medicare Plan	Medicare Advantage Plan
☑ Part A	☑ Part A
☑ Part B	☑ Part B
You can add:	Most plans include:
☐ Part D	☑ Part D
You can also add:	☑ Extra benefits
☐ Supplemental coverage	Some plans also include:
This includes Medicare Supplement Insurance (Medigap). Or, you can use coverage from a former employer or union, or Medicaid.	☐ Lower out-of-pocket costs

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Supplement Plans (Medigaps)

- Higher monthly premiums than Medicare Advantage Plans
- Pays part or all of the remaining costs that Medicare A & B doesn't cover
- Cannot use with Medicare Advantage Plans
- Only covers services that Medicare covers
- Each lettered plan must offer the same benefits (Plans F and G = "Cadillac Plans")

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Advantage vs. Supplement

Medicare Advantage Plan	Medicare Supplement
Monthly premiums are usually lower (Includes A, B and D) No Supplement	Monthly premiums are usually higher (Includes A, B and D) with Supplement
Pay as you go for many services – Deductibles, copays, coinsurance Limits on out-of-pocket costs ($3,900 - $10,000/ year) – assistance needed	Supplement pay for most out-of-pocket costs such as deductibles, coinsurance and copays depending on plan – no assistance needed
Network of doctors and service areas	Can see doctors that accepts Original Medicare
Referral needed for many plans	No referrals for specialists
Prior authorizations for medical benefits are often required	Prior Authorizations for medical benefits are not required
Many offer additional benefits like hearing, vision, or dental	Doesn't offer additional benefits like hearing, vision, or dental

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Identifying a Medicare Advantage Plan

Will have an insurance card other than Medicare Red, White and Blue Card

Primary Coverage	Secondary Coverage
• AARP Medicare Advantage Plan (HMO)	• No secondary coverage
• Aetna Medicare Essential (PPO)	• No secondary coverage
• Humana Gold Choice (PFFS)	• No secondary coverage

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Identifying Medicare with a Supplement

Need to show Medicare Red, White & Blue card and Supplement Card

Primary Coverage	Secondary Coverage
• Medicare A & B	• AARP – UnitedHealthcare Insurance Company
• Medicare A & B	• Mutual of Omaha Insurance Company
• Medicare A & B	• Colonial Penn Life Insurance Company

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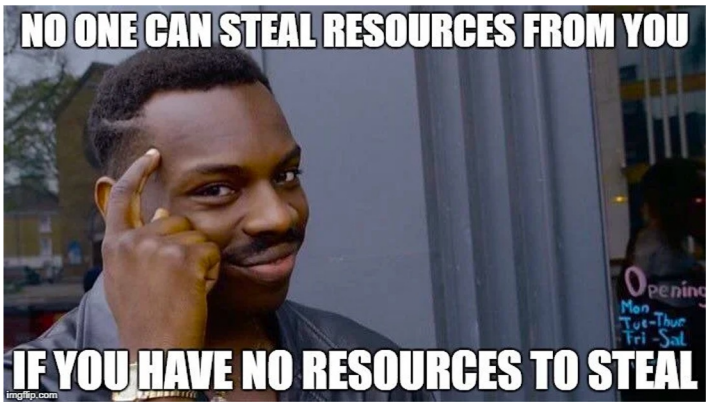
Essential Resources



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Biologics Coordinator - “BC 4eva”

Biologic vs Biologics - there’s more than one med, I choose plural

Designated role signifying the knowledge and expertise of the healthcare team member surrounding medication access specific to specialty medications known as biologics.

I, Elizabeth Johnson, expect a Biologics Coordinator to know:

Access:
Insurance Basics
Local and Regional Payers
Government Payers
Pre-Service Review
White, Clear (Gold), Brown bagging
Fee Schedules and *where to find them*
Policies and Formularies and *where to find them*
Billing and Coding Basics
Denials and Appeals
Copay Assistance
Manufacturer/Hub procedures

Clinical:
Each biologic and their FDA approved indications
Required labs, testing, or imaging
Managing Inventory and Adherence

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BC Metrics

Experience + Volume + Region + Resources(Tech/Support) = Output

Experience: Biologics have seasonal components “End of Year” “Blizzard” “Summer”
Volume: Both number of patients and number of therapies
Region: Payers, health systems, alternate sites, community

Resources -
Tech: Solutions, programs, costs, data
Support: Provider, Manager, Manufacturer

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BC Relationships

WE ARE A HEALTHCARE **TEAM**!

Provider
- Communication and Documentation

Clinical
- Administration and Inventory

Revenue Cycle - Billing, Accounts Receivable, Posting
- Claims and Copay Assistance Utilization

Administrative
- Scheduling and Patient Outreach

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Advocates

Advocates can help patients in every step of the healthcare journey

- Find insurance
- Settle or negotiate billing/coding issues
- Medication access
- Procedures
- Physician relationships
- Family dynamics and treatment or care

Two great examples:

- Greater National Advocates: https://www.gnanow.org/
- National Association of Healthcare Advocacy: https:/www.nahac.com/

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Medicare Benefits Counselors

- Certified through SHIP (State Health Insurance Assistance Programs)
- FREE Medicare benefits counseling in every state
- Counselors do not receive a commission – not insurance brokers
- Goal is to explain all options available to the patient
- For Medicare beneficiaries and those < 65 y/o on disability and eligible for Medicare
- Find SHIP in your state/local area
  - www.seniorsresourceguide.com

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Copay Assistance

Type and requirements vary

- Copay Card
- Coupon
- Patient Assistance Program
- Free Medication Program (Bridge Program)
- Foundations
- Government Programs
- Samples

Not commonly talked about:

- **Compassionate Use** - A way to provide an investigational therapy to a patient who is not eligible to receive that therapy in a clinical trial, but who has a serious or life-threatening illness for which other treatments are not available. (www.cancer.gov)

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Foundations

Foundations are non-profit organizations that provide financial assistance to patients who are under or uninsured.

From Healthwell Foundation, www.healthwell.org:

Our Mission: To reduce financial barriers to care for underinsured patients with chronic or life-altering diseases.

The HealthWell Foundation is a leading non-profit dedicated to improving access to care for America's underinsured. When health insurance is not enough, we fill the gap by assisting with copays, premiums, deductibles and out-of-pocket expenses. In 2021, we awarded more than $818 million in grants through our Disease Funds, and since 2004 we have helped more than 727,000 patients afford essential treatments and medications. HealthWell is recognized as one of America's most efficient charities — 100 percent of every dollar donated goes directly to patient grants and services.

We provide financial assistance to help with:

- Prescription copays
- Health insurance premiums, deductibles and coinsurance
- Pediatric treatment costs
- Travel costs

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Low Income Subsidy (LIS)

- Low Income Subsidy (LIS) = Extra Help
- Program to help people with limited income and resources pay for Medicare drug costs
- Will automatically receive Extra Help if already receiving:
  - Medicaid
  - Medicare Savings Program (MSP) (QMB, SLMB, or QI)
  - Supplemental Security Income (SSI)
- Different Part D plans cover different drugs. If you qualify for Extra Help and your plan doesn't cover a drug you need, you can change Part D plans during these periods:
  - January – March
  - April – June
  - July - September

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Medicare Savings Programs (MSP)

- State helps pay for Medicare costs if patient has limited income and assets
  - Qualified Medicare Beneficiary (QMB)
  - Specified Low-Income Medicare Beneficiary (SLMB)
  - Qualifying Individual (QI)
  - Qualified Disabled and Working Individuals (QDWI)
- Enroll through state Medicaid office
- Some states have online applications

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Medication Assistance for Medicare Patients

- Patients with Medicare Part A:
  - Treat as uninsured patients
  - No coverage for Part B or Part D drugs
  - Apply for free drug for these patients
- Patients with Medicare Part A & B only:
  - Have 20% coinsurance for Part B drugs with no OOP max
  - If Foundation has fund with enough money, could pick up all coinsurances
  - Free drug is usually approved for these patients
  - Help these patients select a Medicare Advantage Plan during Open Enrollment to place a cap on their OOP expenses from the 20% coinsurance from Part B

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Medication Assistance for Medicare Advantage Plan Patients

- Patients with Medicare Advantage Plans may need assistance to help with:
  - Infusions or certain oral medications billed under Part B
  - Deductible
  - 20% coinsurance until they hit their OOP max ($1900 - $10,000)
  - Prescriptions billed under Part D
- Not eligible for all manufacturer copay assistance programs
- Look for open Foundation Assistance first (PAN, Healthwell, etc.)
  - Once OOP max paid, all other services are covered at 100% for remainder of the year
- If no funds available for their disease state, can apply for free drug until a fund opens up – manufacturer will determine their eligibility

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Medication Assistance for Patients with Medicare A, B, D and Supplement

- Typically don't require any assistance for infusions or oral medications billed under Part B
  - Supplement picks up the 20% coinsurance from Part B
- May require assistance for Part D medications
  - Supplement does NOT cover coinsurance for Part D medications
- Try to find foundation assistance first

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State Pharmaceutical Assistance Programs

Virginia

Virginia HIV SPAP

Program Details	
Who is eligible	Available to: Virginia residents participating in the Virginia AIDS Drug Assistance Program with income under 400% FPL and are Part D beneficiaries.
Where to apply	HCS Unit, 1st Floor James Madison Building 109 Governor Street Richmond, VA 23219
Important notes	The State Pharmaceutical Assistance Program (SPAP) pays Medicare Part D costs for people who get medicines through the AIDS Drug Assistance Program (ADAP). All SPAP clients get their Medicare Part D monthly premiums paid. Some SPAP clients get help with their medication copays/coinsurance, deductibles and costs during gaps in coverage (the "donut hole"). Please call the Virginia Department of Health at (855) 362-0658 to apply for the SPAP or if you have questions about enrollment or benefits.
Contact information	(855)362-0658 View program website

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Medicare Insurance Optimization

- For patients with Medicare Part A & B only, get them into a Medicare Advantage plan – can enroll someone in a 5-star plan anytime
- For patients about to turn 65 with cancer or a chronic condition:
  - Encourage patient to purchase a supplement (Medigap)
  - They have 6 months from when they turn 65 to purchase the supplement without being subjected to medical underwriting (can't exclude pre-existing conditions)
  - Higher premiums – we fully insure our vehicles but not ourselves
- When collecting proof of income for other assistance programs, screen Medicare patients for MSP's and LIS

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Copay Card PRO TIP

- Each manufacturer or card processing company has a set allowance for number of days or weeks from date of service they will cover. KNOW THESE, if not ask your local reimbursement manager!
- Submit an EOB even if the claim isn't properly adjudicated! Having a record of the date of service is the most crucial part of the process. Communicate with the processor why there is an issue and what steps are being taken to receive correct payment.

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Complicating Factors

- Co-pay accumulators
- Off label diagnosis
- Step edits
- Income limits

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How to Look at Costs When Considering Care

- Medical Deductible
  - Individual
  - Family
- Co-pay or Co-insurance
- Maximum Out of Pocket
- Patient Assistance

- Pharmacy
  - Formulary
  - Tier
  - Retail or Mail Order
  - Copay Assistance

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Scenario #1

Example: Ricky Bobby visits primary physician (PCP) and needs a pharmacy benefit medication

Benefits:
Medical - $5000 individual deductible and $8500 family, $20 copay for PCP and $50 copay for specialists
Pharmacy - Tiers 1-5, $0-$100

Physician visit allowable: $300, paid $50 specialist copay
Medication prescribed: Tier 5, $100 for 30 days at retail pharmacy or $100 for 90 days mail order, copay card for $25 per dispense 30 or 90 days

Medical Deductible after visit: $4700
Pharmacy: 90 day mail order with copay card for $25

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Scenario #2

Example: Melissa Johnson visits a specialist and needs medication provided by her physician (for ease, scenario is talking about the medication only)

Benefits:
Medical - $10,000 individual deductible (met $1600), 80/20 co-insurance, 100% covered after individual deductible is met
Pharmacy - Tiers 1-4

Physician visit allowable: $150, pays $120 for 80% (deductible now $8280)
Medication prescribed: IV infusion, has $10,000 copay card

First infusion allowable: $5000
Copay card covers patient responsibility of $4000, deductible balance now $4280, copay card balance $6000

Second infusion allowable: $5000
Copay card covers patient responsibility of $4000, deductible balance now $280, copay card balance $2000

Third Infusion allowable: $5000
Copay card covers patient responsibility of $280 (patient covered 100% after meeting deductible), deductible balance now $0, copay card balance $1720

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Questions, comments, discussions… the floor is yours!
Email: ejohnson@namapa.org

- Thank you for your time -

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