After the Treatment Decision

Understanding the access and reimbursement process for specialty rheumatology medications

Genentech
A Member of the Roche Group

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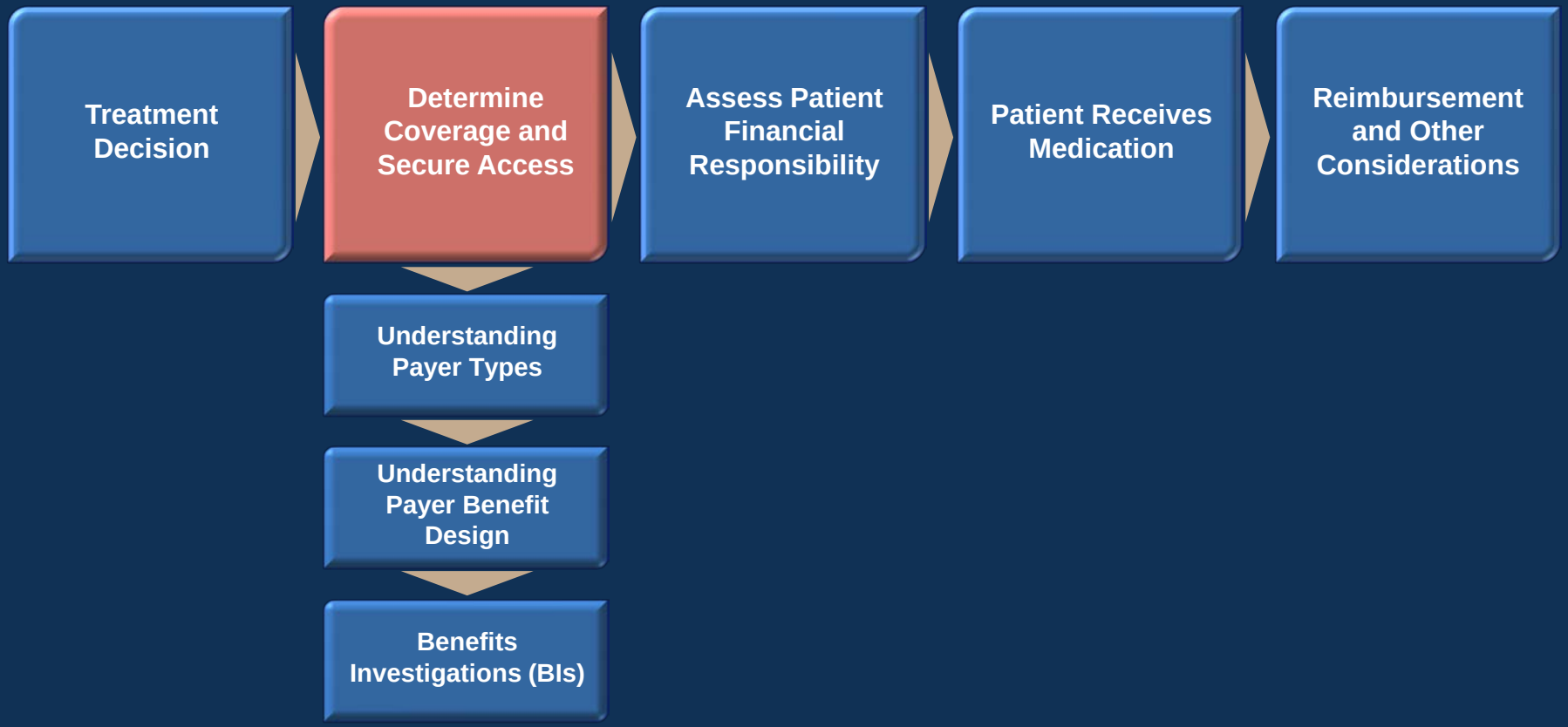
Disclosures

- This program is presented on behalf of Genentech and the information presented is consistent with FDA guidelines
- I have been compensated by Genentech to serve as a speaker for this program
- This program is intended to provide general information about managed care and not medical advice for any particular patient
- This program may be monitored by Genentech for adherence to program requirements

Agenda


Treatment Decision
Determine Coverage and Secure Access
Assess Patient Financial Responsibility
Patient Receives Medication
Reimbursement and Other Considerations

Determine Coverage



Different Types of Payers

Commercial

- Managed care plans
- Qualified health plans (QHPs)*

Public

- Medicare
- Medicaid
- TRICARE

*These are health plans available from the Health Insurance Marketplaces. Some manufacturers may consider QHPs government-sponsored health plans.

Medicare Eligibility

- Medicare covers[1]:
  - People age 65 and older
  - People under 65 who have certain disabilities
  - People with end-stage renal disease

- Dual eligible beneficiaries qualify for both Medicare and Medicaid[2]:
  - Includes Medicare beneficiaries with limited income and resources
  - Get help paying for Medicare premiums and out-of-pocket expenses from Medicaid

More than 40% of rheumatology patients are covered by Medicare.[3]

1. Centers for Medicare & Medicaid Services. https://www.cms.gov/Medicare/Medicare-General-Information/MedicareGenInfo/index.html.

2. Centers for Medicare & Medicaid Services. http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/medicare_beneficiaries_dual_eligibles_at_a_glance.pdf.

3. Data on file. Genentech, Inc. [2005-2010 NAMCS/NHAMCS national survey data].

Parts of Medicare

Medicare Fee-for-Service (FFS)

- **Part A** Hospital Insurance
- **Part B** Medical Insurance
- **Part C** Medicare Advantage
- **Part D** Prescription Drug Coverage

Covers certain doctors' services, outpatient care, office-administered products, medical supplies and preventive services

- Adds prescription drug coverage to Medicare FFS
- Patients covered by Medicare Advantage usually have prescription coverage included in their Medicare Advantage plans

1. Centers for Medicare & Medicaid Services. https://www.cms.gov/Medicare/Medicare-General-Information/MedicareGenInfo/index.html.

Medicare Part D Coverage Gap

- The Medicare Part D coverage gap, or "donut hole" refers to a temporary limit on what the drug plan covers for prescription drugs under Medicare Part D[1]
- In 2015, once a patient reaches $2960 in prescription drug costs (which includes both the patient's cost and the amount paid by the drug plan), the patient is in the coverage gap[1]
- While in the donut hole, the patient pays[1]:
  - **45% of the plan's cost for covered brand-name drugs**
  - **65% of the plan's cost for generic prescription drugs**
- Once the patient's total out-of-pocket (OOP) costs* reach $4700, the patient qualifies for "catastrophic coverage." At that point, the patient is responsible for only a small co-insurance amount or co-pay for covered drugs for the rest of the year[2]
- As a provision of the Affordable Care Act of 2010, the donut hole will narrow gradually until it disappears in 2020[1]

*Although the patient only pays 45%/65% of the price for the drug, 95% of the price—the OOP cost plus the 50% manufacturer discount payment—counts as OOP costs, which helps the patient get out of the donut hole more quickly.[1]

1. Medicare.gov. http://www.medicare.gov/part-d/costs/coverage-gap/part-d-coverage-gap.html.
2. Medicare.gov. http://www.medicare.gov/part-d/costs/catastrophic-coverage/drug-plan-catastrophic-coverage.html.

Medical Benefit vs Pharmacy Benefit

Medical Benefit

- **Typically administered in an office setting by a physician or nurse (IV infusions)**
- Often requires a PA
- Typically has a deductible, then co-insurance (provider collects this payment)
- Provider submits claim to health plan

Pharmacy Benefit

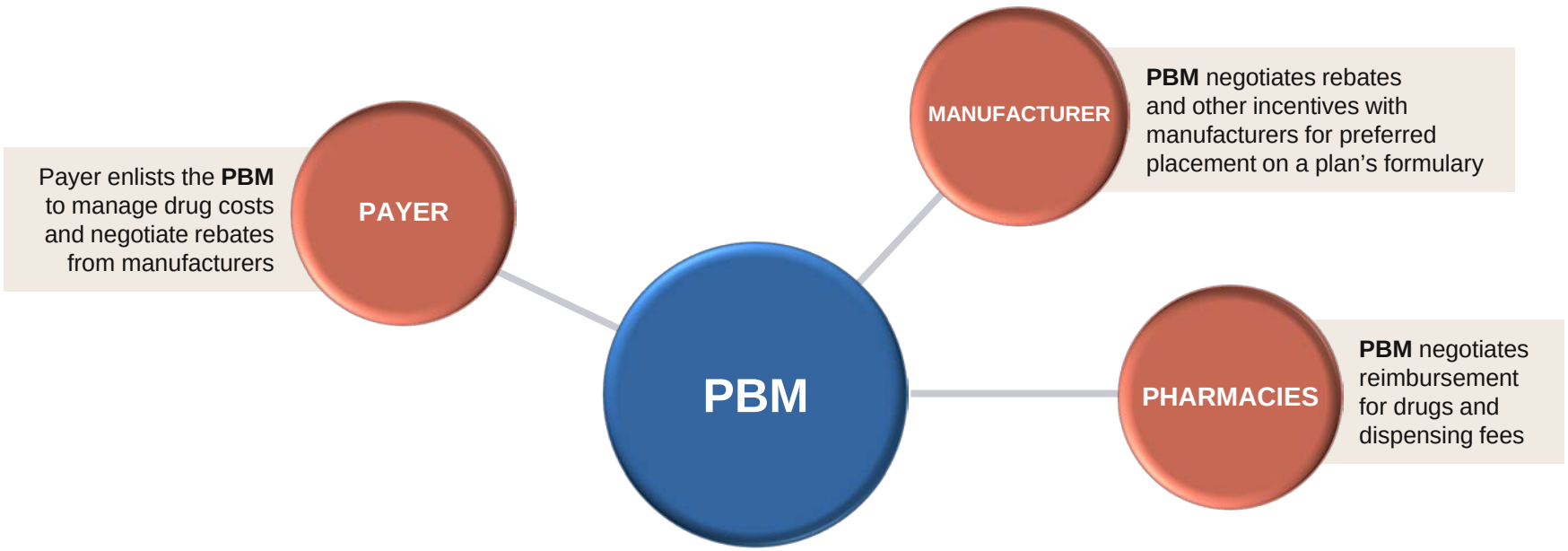
- **Typically self-administered or self-injected by the patient at home**
- Distributed by a specialty, retail or mail pharmacy
- May require a PA
- Typically has a co-pay or co-insurance
- Claim processed through a pharmacy benefit manager (PBM)
- Patient might have a separate insurance card

Buy and Bill vs Specialty Pharmacy (SP)

	Buy and Bill	Specialty Pharmacy
Process	Health care professional (HCP) purchases and bills for a product and its administration to a patient	▪ Collects payment for the product from the patient ▪ Dispenses product ▪ Provides coverage and reimbursement support to HCPs and patients
Drugs typically acquired in this method*	Office-administered products (typically covered under the medical benefit)	Self-administered products (typically covered under the pharmacy benefit)
Order drug	Practice purchases drug directly from a specialty distributor	Delivers patient-specific quantities to the practice (office-administered products) or the patient (self-administered products)
Payment collection	Practice collects the patient's co-pay/co-insurance for the drug and other treatment costs	Collects the patient's co-pay/co-insurance for the drug only
Drug reimbursement	Practice is reimbursed for the drug by the patient's health plan	Bills the patient's health plan for the drug
Additional services	N/A	Might provide specialized services for patients and practices

*This represents how products are typically distributed. There can be variances, depending on the individual practice and the patient's health plan requirements.

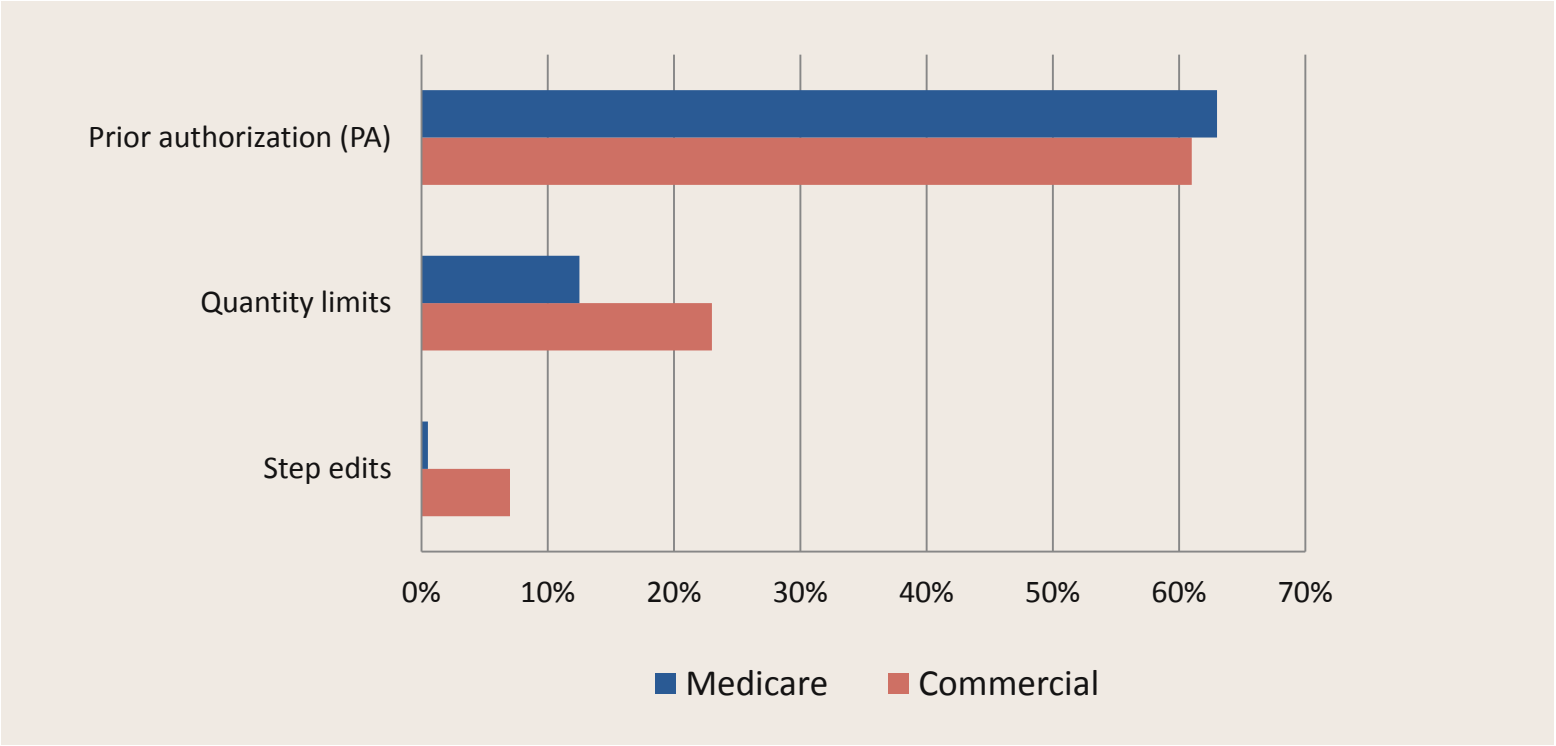
Many Pharmacy Benefit Claims Are Processed Through PBMs



Nearly every prescription drug plan in the United States is administered by a PBM.

1. US Department of Labor. http://www.dol.gov/ebsa/pdf/ACDanzon061914.pdf.

Utilization Management for Select Branded Immunology Products



1. Data on File. Genentech, Inc.

Potential Outcomes and Considerations of Benefits Investigations (BIs)

Potential Outcome	1 Product is covered without restrictions	2 Product is covered with restrictions (eg, PA)	3 Product is not covered
Considerations	▪ What are the patient's OOP costs? ▪ Does the patient require financial assistance? ▪ Does the plan require the use of a particular specialty pharmacy?	▪ What is required for the product to be covered? ▪ What documentation is required?	▪ Why was coverage denied? ▪ What does the plan require for an appeal?

BIs help you determine your patient's coverage, PA requirements and OOP costs for treatment.

Tips for Obtaining a PA if the Product Is Covered With Restrictions

- Understand the payer's guidelines
- Provide correct insurance provider ID and patient ID numbers
- Submit all required supporting documents with the PA request
- Meet all deadlines for submitting the PA request and other required documents
- Keep complete records, including a copy of everything you send and a log of every telephone call you make to the patient's health plan
- Note the time it takes to secure the PA. (This can vary by payer, but is generally 30 to 45 days)
- Check with the payer to determine the length of the approval as this can vary
- **Remember to keep thorough accurate records and save copies of all documentation**

Documenting to Support Clinical Rationale

- Documentation should include a comprehensive rationale for clinical decision making and reflect the indication from the drug's prescribing information
- Include documentation regarding:
  - Disease state
  - Concomitant drugs
  - Line of therapy/failure of previous therapies
  - Age of patient
  - Diagnostic test results
  - Weight of patient

Be as thorough as possible when documenting.

Examples of Documentation for Patient Progress: RA

Rheumatoid Arthritis (RA)

- Routine Assessment of Patient Index Data 3 (RAPID3)
- Health Assessment Questionnaire (HAQ)
- Disease Activity Score (DAS) with 28-joint count (DAS28)
- Simplified and Clinical Disease Activity Indices (SDAI, CDAI)
- American College of Rheumatology (ACR) Core Data Set

1. Walsh N. http://www.medpagetoday.com/Rheumatology/Arthritis/19253.

Examples of Documentation for Patient Progress: GPA and MPA

Clinical assessment

- Cytoplasmic-Antineutrophil Cytoplasmic Antibody/Proteinase 3 (c-ANCA/PR3) blood test[1]
- Perinuclear-Antineutrophil Cytoplasmic Antibody (p-ANCA) blood test[2]
- Other blood tests[1]
- X-rays

Lab tests to evaluate organ involvement and monitor therapy

- Blood tests to check for inflammation and kidney function (creatinine)[2]
- Urinalysis to check for microscopic evidence of blood in the urine[2]
- Myeloperoxidase (MPO) blood test[2]
- Other blood and urine tests[1]

Imaging or biopsies (if indicated)

- Biopsies of the skin, kidney, lung or nerve[2]
- Other tissue biopsies, if needed[1]

GPA=Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis).

MPA=Microscopic Polyangiitis (MPA).

1. Vasculitis Foundation. http://www.vasculitisfoundation.org/education/forms/granulomatosis-with-polyangiitis-gpa-wegeners/.
2. Vasculitis Foundation. http://www.vasculitisfoundation.org/education/forms/microscopic-polyangiitis/.

Preparing an Appeal if the Product Is Not Covered

Compile	▪ Appeal letter ▪ Denial documentation ▪ Medical documentation ▪ Other supporting documentation
Send	▪ Check the payer's policies and deadlines ▪ Send the package to payer via a trackable delivery method to ensure receipt ▪ Keep a copy of the package for your records
Follow up	▪ Find out the result of the appeal

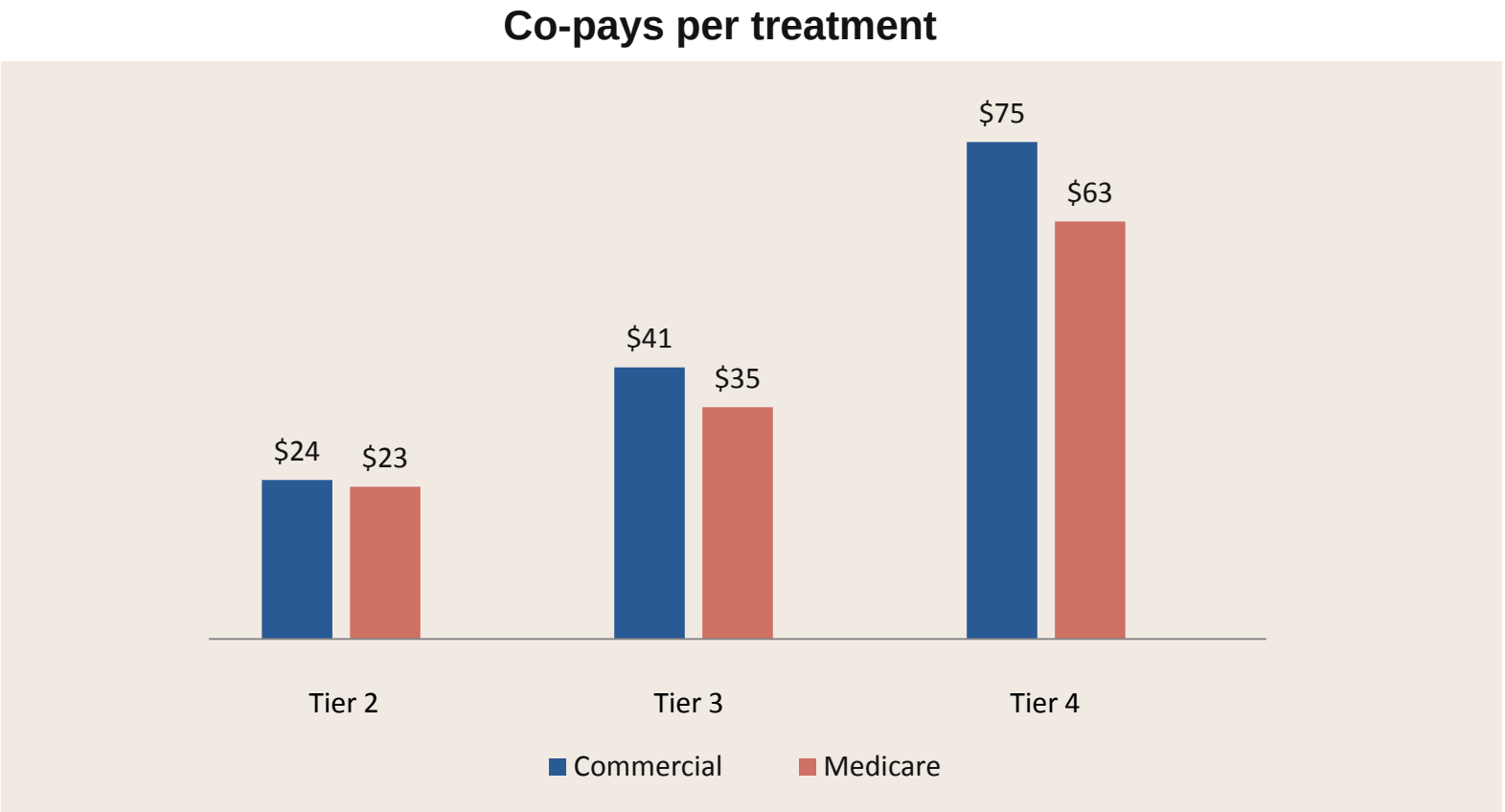
Commonly Requested Documents

PAs and Recertifications	Billing/Providing Medical Necessity	Appeals
▪ Initial history and physical findings ▪ Pathology reports ▪ Prior treatments and response (medication history) ▪ Physician notes ▪ Infusion/injection records ▪ Lab/diagnostic test results	▪ Claim form ▪ Letter of medical necessity ▪ Drug package insert ▪ Infusion/injection records ▪ Office notes ▪ Invoice	▪ Appeal letter ▪ Letter of medical necessity ▪ Denial letter ▪ Initial history and physical findings ▪ Record of prior treatments and response ▪ Imaging studies ▪ Journal articles/textbook excerpts ▪ Practice guidelines

Assess Patient Financial Responsibility

Increasing Patient Co-pays for Select Branded Immunology Products

Assess Patient Financial Responsibility



Patients might also have to pay a co-insurance for products covered on tier 4, resulting in higher OOP costs.

1. Data on File. Genentech, Inc. [Business 1 Formulary Data].

Medicare Costs for 2015[1-3]

Assess Patient Financial Responsibility

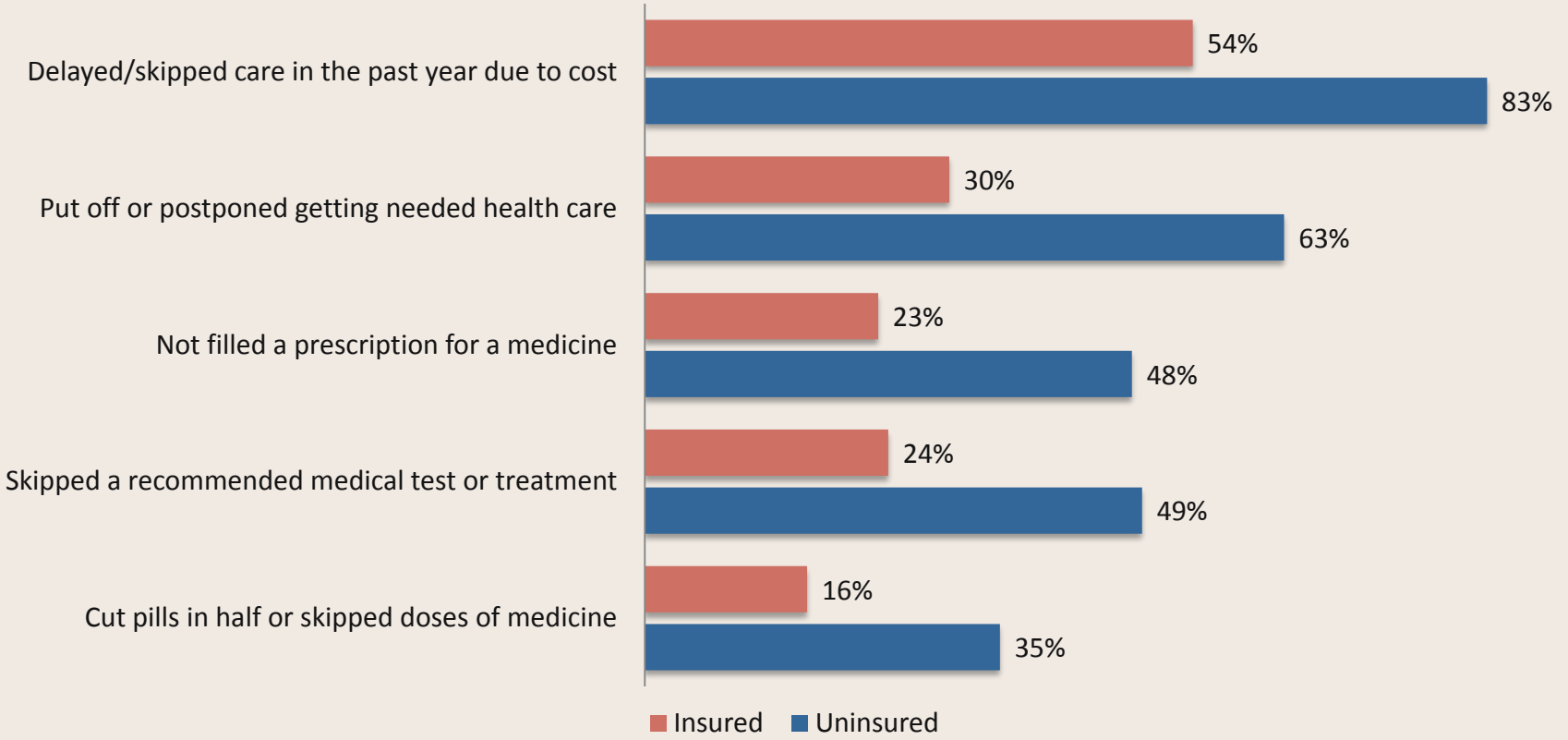
Part B Medical Insurance	Part D Prescription Drug Coverage
▪ Premium is $104.90 per month ▪ Deductible is $147 per year ▪ Co-insurance is 20% for most services ▪ Additional premiums required for Medigap plans **Sample OOP range (co-insurance): $620 to $1026**	▪ Premiums and deductibles vary by plan ▪ Monthly premium adjustments are paid if income is above a certain level **Sample OOP range (co-pay): $18 to $81**

1. Medicare.gov. http://www.medicare.gov/your-medicare-costs/costs-at-a-glance/costs-at-glance.html.
2. Medicare.gov. http://www.medicare.gov/supplement-other-insurance/medigap/whats-medigap.html.
3. Data on File. Genentech, Inc. [Business 1 Formulary Data/average product WAC from Red Book].

Patients Respond to Rising Costs

Assess Patient Financial Responsibility

Problems Accessing and Paying for Health Care in the Past 12 Months



1. Kaiser Family Foundation. http://kff.org/report-section/kaiser-health-tracking-poll-september-2013/.

Discussing the Financial Impact of Treatment

Assess Patient Financial Responsibility

Discuss financial responsibility with patients early in the treatment process

Explore assistance from charitable foundations or government programs

Explore patient assistance from drug manufacturers

Common Patient Assistance Programs

Assess Patient Financial Responsibility

Insurance Status	Patient Assistance Program
Commercially insured	Manufacturer-sponsored co-pay card programs
Publicly or commercially insured	Independent patient assistance foundations
Uninsured	Manufacturer-sponsored free drug programs

Each program has its own eligibility criteria that must be met for patients to receive assistance.

Patient Receives Medication

Alternate Sites of Care

Patient Receives Medication

- Treatment can be administered in the physician's office or an alternate site of care based on whether the practice has:
  - Ability to reconstitute or administer drug
  - Space for administration and patient monitoring
- When using an alternate site of care, the outside facility:
  - Collects the patient's co-pay or co-insurance
  - Is reimbursed for the administration and the cost of the medication

Reimbursement and Other Considerations

Reimbursement Rates

- Medicare uses the Average Sales Price (ASP) model[1]
  - ASP +6% is the standard reimbursement rate[1,2]
  - The Medicare Part B drug fee schedule is updated quarterly[2]
  - Drug manufacturers are required to report the drug ASP, which affects quarterly reimbursement rates[2]
- Rates for private payers vary[3]
  - Depend on contracting
  - Majority of reimbursement rates for branded agents range from ASP +6% to ASP +10%

For ASP drug pricing files, visit www.cms.gov.

1. Mullen P. *Biotechnol Healthc*. 2007;4:48-53.
2. Centers for Medicare & Medicaid Services. http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html?redirect=/mcrpartbdrugavgsalesprice/.
3. The Zitter Group. *The Managed Care Biologicals and Injectables Index*. Fall 2013.

Strategies to Support Claims Submission

Reimbursement and Other Considerations

- Records should be complete and legible[1]
- Confirm both clinician- and patient-supplied information are accurate[2]
- Rationale for services should be documented or easily inferred[1]
- Information should be easily accessible[1]

Assume any and all medical records could be examined at some point during the patient's care.[3]

This description is provided for informational purposes only. The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and health care provider.

1. US Department of Health and Human Services; Centers for Medicare & Medicaid Services. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads//eval_mgmt_serv_guide-ICN006764.pdf.
2. Getting documentation right. http://www.doctorsdigest.net/pdf/0402_04.pdf.
3. World Health Organization/Regional Office for South-East Asia. http://occupationaltherapy2012.files.wordpress.com/2012/03/2007_guidelines_for_clinical_doc.pdf.

Audits

There are several different types of audits:

- Medicare:
  - Recovery Audit Contractors (RACs)
    - Medicare FFS claims are subject to review by a RAC
    - RACs review claims to detect and correct past improper payments
  - Comprehensive Error Rate Testing (CERT)
- Commercial payer audits
- Self-audits from medical societies or Medicare

1. Centers for Medicare & Medicaid Services. http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-Sheets/2008-Fact-Sheets-Items/2008-10-06.html.

Questions?

Thank You