A Guide to Specialty Drugs for Employers

Let's Take Action!

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A Guide to **Specialty Drugs** for Employers: 
*Let's Take Action!*

- Management strategies: Focus on pharmacy
- The medical-pharmacy benefit divide: A cost-management challenge
- Specialty pharmacy services
- Focus on specialty drug-managed condition: Rheumatoid arthritis

Pfizer wishes to acknowledge A. Mark Fendrick, MD, Director of the Center for Value-Based Insurance Design (V-BID) and Brenda Motheral, RPh, MBA, PhD, President of Artemetrx for their contributions in reviewing and helping to shape this publication.
Management strategies: Focus on the pharmacy benefit

- Quantity limits/split fill
- Value-based approach to cost sharing
- Utilization management strategies
- Reimbursement management
Employers can work with plans to implement optimal management strategies

**Plan design**

**Utilization management**

**Reimbursement management**

Employers may need to leverage different types of management strategies

- Depending on whether drugs are billed through the medical benefit or the pharmacy benefit

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Employers can use plan design to help manage costs while supporting appropriate access

Elements of plan design can help

- Prevent drug waste
- Encourage use of clinically appropriate, cost-effective medicines

Overview

Cost and utilization

Value

Adherence

Management strategies

Medical benefit

Specialty pharmacy

Focus on RA

Cost-sharing tiers: Traditional vs specialty drug markets

In the traditional drug market:
Cost-sharing tiers are intended to encourage consumers to choose an effective but less expensive treatment option:
• For example, a generic instead of a brand
• A preferred brand vs a nonpreferred brand

In the specialty drug market:
Cost-sharing tiers may lose their ability to incentivize cost-effective behavior:
• Some specialty drugs may not have therapeutic equivalents
• Even when there is more than one specialty drug option for a therapeutic category, plans may lack adequate evidence to assess comparative value (and define preferred agents)
• In some categories, the lack of competition gives consumers only 2 options:

Pay high costs or Forgo therapy

For specialty drugs, a more nuanced approach to cost sharing may be needed.

Premera Blue Cross Blue Shield has developed a value-based formulary that attempts to align consumer cost-sharing with the overall value of medication.\(^1\)

Drugs are assigned to tiers based on a multifactorial assessment.\(^1,2\)

- Safety and efficacy
- Benefit vs other available treatment options
- Cost of drug
- Impact of treatment on total cost of care, for example,
  - Patient's quality of life and functional status
  - Need for use of other health care resources

DEFINING VALUE\(^2\):

- Utilization of other health care resources
- Quality of life
- Clinical outcomes

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Utilization management supports safe and cost-effective access to therapy

Utilization management
• Promotes medically appropriate and safe use of drugs
• Aims to reduce costs while maintaining or improving quality of care

Strategies include

Management strategies
Cost and utilization
Value
Adherence

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Specialty pharmacy
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Reimbursement management can help employers cope with the high costs of specialty drugs

Monitor claims for payment accuracy

- Ensure claims are paid at contracted rates

Work with PBMs to ensure appropriate rebates are shared with the employer

- Evaluate rebates in terms of cost-effectiveness
  - A lower-cost product may be a better value than a higher-cost product with a rebate

Managing access and cost through the medical benefit can be especially challenging

Approximately 15% to 20% of specialty drug requests through the medical benefit are not in agreement with evidence-based treatment guidelines.

Claims management tools applied to the medical benefit could save payers up to $1.9 billion annually.
The medical-pharmacy benefit divide
A cost-management challenge

Lack of precision in medical benefit coding
Channel management
Site-of-care challenges
Strategies to manage site of care
Reimbursement management
The medical-pharmacy split for specialty drug spend is about 50-50, but the breakdown varies by therapeutic category.

Almost 50-50 medical-pharmacy benefit split or specialty drug spend

But the proportion of medical benefit billing varies by therapeutic category

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UnitedHealth Group, 2012, fully insured commercial plans.

### Modes of administration may influence benefit coverage

<table>
<thead>
<tr>
<th>Infused therapies</th>
<th>Oral agents</th>
<th>Injectables (SC or IM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• More likely to be covered under <strong>medical</strong> benefit¹</td>
<td>• More likely to be covered under <strong>pharmacy</strong> benefit¹</td>
<td>• More likely to be covered under <strong>pharmacy</strong> benefit¹</td>
</tr>
<tr>
<td>• Site of care is a cost-management challenge¹</td>
<td>• Some new oral drugs can be more expensive than some infused agents¹</td>
<td>• May be self-administered or administered by health care professional¹</td>
</tr>
</tbody>
</table>

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**IM**= intramuscular; **SC**= subcutaneous.


Lost dollars related to specialty drugs billed through the medical benefit

2011: $5 billion

2015 (projected): $9 billion

Contributors to wasteful spending through the medical benefit

- Suboptimal management of channels and site of care
- Inaccurate billing or payment of claims
- Inadequate utilization management

Drug costs can vary substantially by site of care

$2 billion

An estimated $2 billion could be saved through efficient reimbursement management strategies

15%–20%

Approximately 15% to 20% of specialty drug requests through the medical benefit do not meet evidence-based treatment guidelines

Management of medical drug spend is complicated by lack of specificity in medical benefit billing

**Drugs billed through the medical benefit**

Claims for drugs billed under the medical benefit use J code 1

- J codes are less-specific identifier than NDC codes 2
  - Unique only to the drug's chemical name

**J-code billing lacks precision**  
- Brands and generics share codes
- New drugs may have temporary or miscellaneous codes
- Package size not indicated

**Drugs billed through the pharmacy benefit**

Drugs are identified by an NDC, which specifies 1

- Drug name
- Manufacturer
- Dosage form
- Strength
- Package size

NDC= National Drug Code.

Because specific drug costs are not associated with J codes, it is difficult to track and manage utilization.

Identical J codes mask differences in costs related to site of care

<table>
<thead>
<tr>
<th>Code</th>
<th>Drug</th>
<th>Per-unit cost</th>
<th>Percent difference in per-unit cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1745</td>
<td>Remicade®</td>
<td>• $63/ATS</td>
<td>103%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• $129/outpatient facility</td>
<td></td>
</tr>
<tr>
<td>J2323</td>
<td>Tysabri®</td>
<td>• $8/ATS</td>
<td>60%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• $13/outpatient facility</td>
<td></td>
</tr>
</tbody>
</table>

ATS = alternative treatment site.
Per-unit cost difference based on Walgreens' internal analysis of over 5 million commercially insured individuals in 2010.

Remicade (infliximab) is a registered trademark of Janssen Biotech, Inc.
Tysabri (natalizumab) is a registered trademark of Elan Pharmaceuticals.
Traditional tools may be useful for managing cost and access in the medical benefit

But these strategies may be more difficult to apply in the setting of specialty drugs typically covered by the medical benefit.

And management tools will need to be tailored to:

- Specific characteristics of specialty drugs covered under the medical benefit
- Characteristics and preferences of affected patient populations
- Attitudes of provider populations
- Impact of site of care

Medical carve-out is another way of describing the transfer of some specialty drugs from the medical channel to the pharmacy channel.1

Drugs may be “carved out” from medical benefit coverage

• Using disease-specific criteria2
• Based on mode of administration3

Different types of dispensing options may occur with medical carve-outs

• Brown bagging (patient picks up drug)4
• White bagging (specialty pharmacy delivers drug)5,6

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The pharmacy benefit may offer advantages over the medical benefit

The pharmacy benefit

- Is associated with less variation in price than the medical benefit
- Facilitates comparison of different therapeutic options for the same condition
- Traditional utilization and cost-management tools (eg, prior authorizations, cost-sharing tiers) are well integrated

<table>
<thead>
<tr>
<th>Pharmacy</th>
<th>Medical</th>
</tr>
</thead>
<tbody>
<tr>
<td>The pharmacy benefit all was real-time adjudication and medication review</td>
<td></td>
</tr>
<tr>
<td>Quantity errors, PAs, early refills risk of drug interactions or adverse events</td>
<td></td>
</tr>
<tr>
<td>In the medical benefit the review process may involve</td>
<td></td>
</tr>
<tr>
<td>A manual process in response to physician request for a PA</td>
<td></td>
</tr>
<tr>
<td>A retrospective review after claim submission</td>
<td></td>
</tr>
</tbody>
</table>

PA= prior authorization.

But there may be advantages to keeping some drugs categorized under the medical benefit

Privately owned medical practices may be able to purchase drugs at lower prices\(^1\)\(^2\)

- If the buyer shares savings with the employer, the drug cost could be lower than through the pharmacy benefit

Consumers may have lower out-of-pocket costs under the medical benefit\(^1\)

With some drugs, the ability to bill for a partial dose under the medical benefit may help reduce waste\(^1\)

- For example, with cancer drugs

Moving some specialty drugs to pharmacy (a medical carve-out) may

- Introduce disruptions in care and process for patients and providers\(^1\)
- Complicate the provider’s ability to adjust dosage for infused drugs, especially cancer drugs\(^1\)

Remicade is a biologic used to treat rheumatoid arthritis and other conditions
- It is administered by infusion
- It is typically covered under the medical benefit

Humira and Enbrel are biologics also used to treat rheumatoid arthritis
- They are administered by self-injection
- They are typically covered under the pharmacy benefit

Moving Remicade to the pharmacy benefit
- Would facilitate comparison of available treatment options for rheumatoid arthritis

Retaining Remicade in the medical benefit
- Could result in lower costs to the employer if providers can obtain the drug at a lower cost and they pass savings on to payer

Wehrwein P. Should specialty drugs be shifted from medical to pharmacy benefit? Managed Care January 2015.
Switching drugs from medical to pharmacy is a complex undertaking

Analyze specialty drug pricing across medical and pharmacy benefit

- This can be a complex process that involves integrating J-code claims (medical benefit) with NDC claims (pharmacy benefit)

Consider the suitability of the therapeutic target for channel management

- Infused cancer drugs have not typically been a good target due to provider resistance and potential for care disruptions

Ensure adequate infrastructure to support claims payment

- Double billing/payment may occur because some drugs are covered under both channels
- Frequent audits can help avoid payment problems

Site of care = the location at which infused or injected drugs are actually administered to patients

Traditional infusion sites
- Inpatient or outpatient hospital facility
- Skilled nursing facility

Alternative treatment sites (ATS)
- Patient’s home
- Physician’s office
- Specialty pharmacy or other ancillary site
  - Freestanding infusion clinic
  - Worksite or retail clinic

Distribution of total spend through the medical benefit

UnitedHealth Group, 2012, fully insured commercial plans.

The significance of the site-of-care issue varies according to therapeutic category

Distribution of total spend through the medical benefit

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Focus on RA

UnitedHealth Group, 2012, fully insured commercial health plans. Includes therapeutic categories that represent > 10% of total spending on specialty drugs.

ESRD = end-stage renal disease; IBD = inflammatory bowel disease; MS = multiple sclerosis; RA = rheumatoid arthritis.
Site of care can be a challenging cost-management issue

Artemetrx analysis of impact of site of care

Cost of specialty drug acquisition

<table>
<thead>
<tr>
<th>Site of Care</th>
<th>Cost of Specialty Drug Acquisition Percentage of Average Sales Price (ASP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital outpatient</td>
<td>227%</td>
</tr>
<tr>
<td>Physician office</td>
<td>107%</td>
</tr>
</tbody>
</table>

Cost of specialty drug administration

<table>
<thead>
<tr>
<th>Site of Care</th>
<th>Cost of Specialty Drug Administration Average Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital outpatient</td>
<td>$605</td>
</tr>
<tr>
<td>Physician office</td>
<td>$1</td>
</tr>
</tbody>
</table>

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Adapted with permission from Motheral BR. Site of care management. Presented at Specialty Rx – Identify, Understand, and Manage the Cost sponsored by Mid-America Coalition on Health Care, July 31, 2014.
Site-of-care management: Cost variations across settings

Costs for both drug and administration of drug differ across sites¹

- Costs are highest in outpatient hospital settings

Example: Remicade

Drug cost by site of service

<table>
<thead>
<tr>
<th>Site of Service</th>
<th>Drug Cost</th>
<th>Administration Cost</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home</td>
<td>$3259</td>
<td>$148</td>
<td>$3407</td>
</tr>
<tr>
<td>Office</td>
<td>$2508</td>
<td>$265</td>
<td>$2773</td>
</tr>
<tr>
<td>Hospital outpatient*</td>
<td>$5393</td>
<td>$425</td>
<td>$5818</td>
</tr>
</tbody>
</table>

CVS Caremark internal data, 2013.

¹When medical practices are purchased by a hospital, costs may be comparable to hospital outpatient facility costs.²


Optimal site-of-care management could save employers an estimated 12% to 34% of medical drug spend\(^1\)

Review claims data to identify infusions taking place at high-cost facilities\(^3\)

Identify cost-effective alternative sites of care that are
- Clinically appropriate\(^1\)
- Convenient for the patient\(^2\)

Conduct outreach to patients and providers
- Engage physicians in selection of sites\(^1\)
- Provide education, information, and incentives to encourage patients to switch to a lower-cost site\(^2\)

Support site-of-care management with an adequate ATS network\(^5\)
- Adequate geographic coverage to meet patients’ needs
- Access to trained infusion nurses with expertise in specialty drug infusion

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Align cost-sharing and incentive policies to support cost-effective behavior across stakeholders

Use of alternative sites of care supports payers’ cost-management priorities

• Consumer and physician incentives should be aligned to support those priorities

 Consumers

When consumers voluntarily switch to an alternative site

• Out-of-pocket costs should decrease or be eliminated

Financial incentives are an appropriate option to encourage consumers to switch

Review consumer cost sharing for drugs across sites

• Is cost sharing aligned with cost-effective choices?

 Providers

Involve providers in site-of-care management using strategies such as

• Shared-savings programs
• Pay-for-performance incentives

Collaboration through data sharing and transparent reporting can help align payer-provider interests
Variations in pricing across settings underscore importance of reimbursement management

Evaluate vendor contracts¹ ²
- Assess physician/facility reimbursement for specialty drugs
- Negotiate rates in medical vendor contracts
  - For specialty drug prices
  - For drug administration fees

Identify and correct payment errors¹
- Monitor claims on a routine basis to ensure claims are paid at negotiated rate

Quantity errors are common with specialty drug claims¹
- Identifying the correct billing unit for infused products can be difficult
- Compare billed quantities with dosing standards

An estimated $2 billion could be saved through a robust reimbursement management program

Utilization management strategies can support cost-management efforts

**Apply prior authorization strategies across benefits when feasible**
- To ensure that individuals are receiving the most appropriate, cost-effective therapy

**Post-service reviews may be more practical for drugs covered under the medical benefit**
- Confirm clinically appropriate doses and recommended frequency of drug administration
- Confirm accurate pricing for dose and drug

**Ensure evidence-based use of therapy**
- Require proof of appropriate diagnostic testing

**Establish a stepped-therapy protocol**
- For example, self-injectable drugs preferred over infused drugs, when clinically appropriate

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Specialty pharmacy services

What is specialty pharmacy?
Patient-centered support and services
Support for employer priorities
Effect of specialty pharmacy services in patients taking oral cancer drugs
What is a specialty pharmacy?

Specialty pharmacies dispense specialty medications using a high-touch approach that provides support and services aligned with:

- Patient needs
- Employer priorities

### Drugs dispensed through the specialty pharmacy channel

1. **Rx** → patient
2. **Rx** → provider → patient
3. **Rx** → patient → provider

**In some communities, drugs may be delivered to patients or providers by mail.**

**Some specialty pharmacy programs allow patients to pick up prescriptions from their affiliated local pharmacies.**

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A full-service specialty pharmacy offers a patient-centered approach to management

Specialty pharmacies proactively manage health care needs of patients with chronic and/or complex conditions.

Recommended services include

- Management of prior authorizations and review of patient eligibility for therapy according to evidence-based guidelines
- Monitoring of appropriate dose and therapeutic efficacy
- Distribution of specialty drugs to patients or providers, as appropriate
  - Access to limited-distribution drugs
- 24-hour patient access to support (nurses or pharmacists)
- In-place systems for providing emergency supplies or replacement of lost packages
- Reimbursement management/assistance for employers and employees

Specialty pharmacies provide individualized services to support patients

Adherence support
- Refill reminder calls

Appropriate patient education and self-management support
- Condition-specific information
- Injection training, when appropriate
- Training on recognizing and coping with therapy-related side effects

Financial assistance
- Reimbursement processes
- Co-payment assistance

Specialty pharmacies offer access to comprehensive, disease-specific management

Specialty pharmacies offer disease-specific and drug-specific care management services.

Programs may be offered through **Centers of Excellence (COEs)**

- Disease-specific organizations that offer comprehensive, targeted services

**COEs are staffed by**

- Patient care coordinators
- Reimbursement specialists
- Specially trained pharmacists

**Services include**

- Medication reviews
- Patient education
- Financial guidance
- Comprehensive view of patient care needs

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Specialty pharmacies also support employer priorities

**Reimbursement management**
- Accurate payment of claims
- Optimal use of appropriate rebates

**Pricing discounts**

**Site-of-care management**

**Preferred product approach**

**REMS management programs**

Specialty Pharmacies

**Overview**
**Cost and utilization**
**Value**
**Adherence**
**Management strategies**
**Medical benefit**
**Specialty pharmacy**
**V-BID**

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Specialty pharmacies can help employers manage cost and utilization using comprehensive data

Data collection and reporting support quality improvement efforts.

Some specialty pharmacies may be able to integrate claims data across benefit channel

- Supports site-of-care management

Specialty pharmacies may be able to provide follow-up data on patients and outcomes

- To track interventions and outcomes
- To document savings related to drug costs and total health care costs

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An optimal relationship with a specialty pharmacy depends on a well-designed contract

Important contractual issues include, but are not limited to:

<table>
<thead>
<tr>
<th>Definitions of specialty drugs covered under the contract</th>
<th>Clinical fees</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rebates</td>
</tr>
<tr>
<td></td>
<td>Discounts</td>
</tr>
<tr>
<td></td>
<td>Quality standards</td>
</tr>
<tr>
<td></td>
<td>Dispensing fees</td>
</tr>
<tr>
<td></td>
<td>Administrative fees</td>
</tr>
</tbody>
</table>

Specialty pharmacies should provide employers with performance guarantees based on their contracted services.

Specialty pharmacy services were associated with reduced health care costs in patients taking oral cancer drugs

Total health care costs were 13% lower in the specialty pharmacy group vs the retail pharmacy group

- Total costs = total pharmacy + inpatient + outpatient costs
- $97,156 (retail) - $84,105 (specialty) = $13,092 (P = 0.02)
- Showed better adherence: 66% vs 58%, P < 0.001 (assessed by weighted MPR)
- Had 35% fewer medication gaps, P < 0.001 (defined as ≥60 days without study medications)

### Breakdown of mean total health care costs per patient per year

<table>
<thead>
<tr>
<th>Inpatient outpatient costs</th>
<th>Retail pharmacy</th>
<th>Specialty pharmacy</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral cancer drug costs</td>
<td>$61,137</td>
<td>$45,696</td>
<td>−$15,440</td>
</tr>
<tr>
<td></td>
<td>$29,654</td>
<td>$32,545</td>
<td>+$2891</td>
</tr>
</tbody>
</table>

Designated specialty pharmacy program offered through employer-sponsored plans for patients taking oral cancer drugs (imatinib, sorafenib, lenalidomide, erlotinib, and “other”). Eligible patients were identified using the 2007 United Healthcare administrative claims database. Outcomes represent findings 1 year after implementation of the program in the specialty pharmacy (n= 464) and retail pharmacy (n= 464) groups. Tschida SF et al. Am J Pharm Benefits. 2012;4(4): 165 - 174.
Focus on specialty drug-managed condition: Rheumatoid arthritis

What is rheumatoid arthritis?
Who gets rheumatoid arthritis?
Suggestive symptoms
Diagnostic approach
Impact on functional status and disability
Disease-related direct and indirect costs
Treatment options
What is rheumatoid arthritis?

Rheumatoid arthritis (RA) is an autoimmune disease.

A normally functioning immune system protects us from infections. In RA, the immune system goes awry and mistakenly attacks the joints, causing inflammation, which leads to thickening of the inner lining of the joint (called the synovium).

In RA, the immune system attacks joints, causing pain and inflammation.

Early joint symptoms may include tenderness, pain, and swelling, especially in joints of the hand.

As RA progresses, patients may experience:

- Joint erosion and damage
- Whole-body symptoms (e.g., fatigue, loss of appetite)

Patients with RA are also at risk for systemic effects.

- For example, affecting the skin, heart, and lungs

Who gets rheumatoid arthritis?

RA affects about 1.5 million individuals in the United States.

Most common in older adults, with highest onset in individuals in their 60s.
- But it may begin in middle age.
- Older teenagers and young adults may also be affected.

The risk of developing RA is higher in the presence of certain modifiable risk factors:
- Smoking
- Obesity

Women tend to develop RA more often, and earlier, than men.

RA is 2 to 3 times more common in women than in men.
- Women make up about 75% of the RA population.

RA may have an earlier onset in women.
- In women, RA typically begins between the ages of 30 and 60.
- In men, RA typically occurs later in life.

# Rheumatoid arthritis vs osteoarthritis

<table>
<thead>
<tr>
<th>Rheumatoid arthritis</th>
<th>Osteoarthritis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Affects ~ 1.5 million adults in the US&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Affects ~ 27 million adults in US&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td>• Prevalence: 0.72%&lt;sup&gt;1&lt;/sup&gt;</td>
<td>• Prevalence: 12%&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>Autoimmune response induces inflammation of the synovium (tissue that lines the joint)&lt;sup&gt;3&lt;/sup&gt;</td>
<td>Mechanical wear and tear on joint&lt;sup&gt;6&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>causes deterioration of cartilage and bone overgrowth&lt;sup&gt;4,5&lt;/sup&gt;</td>
</tr>
<tr>
<td>Relatively rapid onset at any age&lt;sup&gt;4&lt;/sup&gt;</td>
<td>Slow onset, usually beginning later in life&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
<tr>
<td>Characterized by pain, swelling, and stiffness of joints&lt;sup&gt;4&lt;/sup&gt;</td>
<td>Characterized by aching and tenderness of joints, but little or no swelling&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
<tr>
<td>Symmetric joint involvement: same joints on both sides of body&lt;sup&gt;6&lt;/sup&gt;</td>
<td>May affect a single joint&lt;sup&gt;6&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>May be dominant on one side of body&lt;sup&gt;6&lt;/sup&gt;</td>
</tr>
<tr>
<td>Fatigue and other whole-body symptoms&lt;sup&gt;4&lt;/sup&gt;</td>
<td>Absence of whole-body symptoms&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

Is it rheumatoid arthritis?

Symptoms that suggest RA

- Joint pain, tenderness, swelling, or stiffness for 6 weeks or longer
- Morning stiffness for 30 minutes or longer
- More than 1 joint affected
- Small joints (e.g., wrists and certain joints of the hands and feet) are affected
- Same joints on both sides of the body are affected
- Pain may be accompanied by loss of appetite, fatigue, and low-grade fever

Comorbidities are common in patients with rheumatoid arthritis

Patients with rheumatoid arthritis have increased risks for

- **Cardiovascular disease**: Especially ischemic disease
- **Diabetes**: Both type 1 and type 2 diabetes
- **Infections**: Most commonly tuberculosis
- **Malignancies**: For example, leukemia, lymphoma, and multiple myeloma
- **Mental health conditions**: Anxiety and depression

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Rheumatoid arthritis imposes a heavy burden on affected individuals

Individuals with RA report significant functional limitation*

Individuals with RA vs individuals without arthritis

- About 40% more patients with RA reported needing help with personal care
- Almost 50% more patients with RA experienced health-related activity limitations

Rate of work-related disability in patients with RA increases over time†

<table>
<thead>
<tr>
<th>Time from diagnosis</th>
<th>1 year (study entry)</th>
<th>5 years</th>
<th>10 years</th>
<th>15 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate of disability</td>
<td>28%</td>
<td>35%</td>
<td>39%</td>
<td>44%</td>
</tr>
</tbody>
</table>

*Based on responses to the CDC’s Health-related Quality of Life (HRQOL) modules from older, low-income adults in Pennsylvania (n = 31,000 with no arthritis diagnosis; n = ~1000 with diagnosis of RA).
†Data reported in a study of 148 patients with early RA at study entry who were followed up for 15 years. All subjects were of working age at study entry.
Rheumatoid arthritis exposes both employers and employees to high costs

RA is costly to treat, but indirect costs can be even higher than direct treatment costs

### Annual excess costs related to RA\(^1,2\)*

<table>
<thead>
<tr>
<th>Employer</th>
<th>Employee</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Direct costs for</strong></td>
<td><strong>Indirect costs for</strong></td>
</tr>
<tr>
<td>• Drug</td>
<td>• Disability</td>
</tr>
<tr>
<td>• Physician/facility fees</td>
<td>• Absenteeism and presenteeism</td>
</tr>
<tr>
<td>• Co-payments</td>
<td>• Training and replacement</td>
</tr>
<tr>
<td>• Coinsurance</td>
<td>• Workplace adaptations</td>
</tr>
</tbody>
</table>

### Direct costs:
- $10.6 billion

### Indirect costs:
- $13 billion

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\(^*\)Analysis of administrative claims covering private and Medicare/Medicaid beneficiaries in the United States. Dollar amounts from 2005 have been adjusted to 2013 values. Costs represent the excess costs for payers and patients compared with matched controls without RA.

Treatment goals

- Relieve pain
- Reduce inflammation
- Slow down or stop joint damage
- Improve patient’s sense of well-being and maintain ability to function

Important goal: To prevent joint erosion

- Because there is no evidence that RA-related bone damage can be repaired

Treatment options

Lifestyle modification
- Rest and exercise
- Healthy diet
- Stress reduction

Medications
- To relieve signs and symptoms
- To intervene in the disease process

Surgery
- Joint replacement
- Fusion (arthrodesis)
- Tendon reconstruction

Available medical options for treatment of rheumatoid arthritis

Relieve pain / Reduce inflammation

- Oral anti-inflammatory painkillers (e.g., aspirin, NSAIDs)
- Topical pain relievers
- Corticosteroids

Slow disease progression

- Conventional DMARDs (e.g., hydroxychloroquine, leflunomide, methotrexate, and sulfasalazine, )
- TNF blockers (e.g., Humira and Enbrel)
- Non-TNF blockers
  - Biologic (e.g., Orencia® and Rituxan®)
  - Oral (JAK inhibitors)

DMARDs = disease-modifying antirheumatic drugs; JAK = Janus kinase; NSAID = nonsteroidal anti-inflammatory drug; TNF = tumor necrosis factor. Orencia (abatacept) is a registered trademark of Bristol-Myers Squibb. Rituxan (rituximab) is a registered trademark of Biogen Idec, Inc.

Approach to treatment

Treat to Target in the Management of RA

- 20%-30% become permanently work disabled if not treated within 2-3 years of diagnosis
- ~40% have moderate to high disease activity
- <34% of HCPs measure and report disease activity and/or functional status

Overview
Cost and utilization
Value
Adherence
Management strategies
Medical benefit
Specialty pharmacy
Focus on RA

3. Based on analysis of national data on Medicare fee-for-service beneficiaries (2007-2009)
Patients Can Be Categorized Into 1 of 4 Disease Activity Levels

<table>
<thead>
<tr>
<th>Activity Level</th>
<th>RAPID3 (range 0-30)</th>
<th>DAS28 (range 0-10)</th>
<th>CDAI (range 0-76)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Activity</td>
<td>&gt;12</td>
<td>&gt;5.1</td>
<td>&gt;22</td>
</tr>
<tr>
<td></td>
<td>Change therapy or have a good reason not to</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate Activity</td>
<td>6.1-12</td>
<td>3.21-5.1</td>
<td>10.1-22</td>
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<tr>
<td></td>
<td>Strongly consider change in therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Activity</td>
<td>3.1-6</td>
<td>2.6-3.2</td>
<td>2.9-10</td>
</tr>
<tr>
<td></td>
<td>Consider change</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Near Remission</td>
<td>≤3</td>
<td>&lt;2.6</td>
<td>≤2.8</td>
</tr>
<tr>
<td></td>
<td>Therapy working</td>
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<td></td>
</tr>
</tbody>
</table>

Alignment of stakeholders is important (Rheumatologist, Patient, PBM, Specialty Pharmacy, Health Plan, Disability, Employer)

- Use of same disease activity language
- Dedication to a repeatable, action-oriented process will drive success in treating to target: Set the Target - Treat - Assess - Adjust - Repeat

DAS28 = Disease Activity Score for 28 joints; RAPID3 = Routine Assessment of Patient Index Data 3.

Additional thoughts to consider

Provide access to a range of treatment options

- When designing benefits for the needs of people with rheumatoid arthritis, keep in mind that as RA progresses, patients often need to change doses, change agents or go on combination therapy.

Understand the impact of site-of-care on medical or pharmacy costs

Measures for controlling costs should consider:

- A total cost-of-care approach
- Mode of administration
- Cost of the drug itself as well as costs associated with the site of care

References:

QUESTIONS?