Trends in Biologic Therapies for Rheumatoid Arthritis: Results from a Survey of Payers and Providers

March/April 2012, Vol 5, No 2 - *Business*

Rhonda Greenapple, MSPH

Abstract

Background: Advances in therapies for rheumatoid arthritis (RA), particularly biologics, have transformed the treatment paradigm for RA. However, the associated costs of these therapies result in a significant economic burden on the healthcare system. As a chronic disease requiring lifelong treatment, most health plans now position RA drugs as a high-priority therapeutic category.

Objective: To identify provider and payer practices and perceptions regarding coverage of RA biologics in the current marketplace, as well as emerging trends in reimbursement practices.

Methods: In November 2011, Reimbursement Intelligence, a healthcare research company, collected and analyzed quantitative and qualitative data via parallel-structure online surveys of 100 rheumatologists and 50 health plan payers (medical and pharmacy directors) who represent more than 80 million covered lives. The surveys included approximately 150 questions, and the surveys were designed to force a response for each question.

Results: Payers reported using tier placement, prior authorization, and contracting in determining coverage strategies for RA biologics. Among providers, experience with older RA agents remains the key driver for the choice of a biologic agent. A majority of payers and providers (68% and 54%, respectively) reported that they did not anticipate a change in the way their plans would manage biologics over the next 2 to 4 years. Payers' responses indicated uncertainty about how therapeutic positioning of newer, small-molecule drugs at price parity to biologics would affect the current reimbursement landscape. Survey responses show that approval of an indication for early treatment of RA is not likely to change the prescribing and reimbursement landscape for RA biologics. This survey further shows that payers and providers are

treatments for RA.

Conclusion: Advances in RA therapies allow patients increasing options for effective disease management. However, the high cost of biologic therapies and the need for lifelong treatment raise economic concerns. Payer satisfaction with current therapies and uncertainty about added value of new therapies will create challenges for new medications coming to market.

Am Health Drug Benefits. 2012;5(2):83-92

Rheumatoid arthritis (RA) is a chronic systemic autoimmune disorder and the most common form of inflammatory arthritis.[1] RA affects 1% of the population, most often adults aged 40 to 70 years.[2] Recent epidemiologic data indicate that the incidence of RA in women has risen in the past 10 years.[3] Because RA affects many individuals who are of working age and remains a major cause of disability, the economic burden of RA adds a significant cost not only to patients and their families, but also to society as a whole.[1,4] In addition, reduced quality of life, loss of work productivity, and substantial healthcare utilization are factors that must be considered in RA management.[4,5]

Because complications of RA may begin to develop within months of disease onset, early and aggressive treatment is considered clinically necessary to manage immediate symptoms of pain associated with inflammation, but also to slow disease progression to prevent longterm disability.[1,6,7] Historically, estimates of work disability rates for RA have been high, with higher rates associated with longer disease duration; work disability estimates have been shown to reach 30% within 2 to 3 years of diagnosis.[4,5] Recent estimates suggest that RA-related work disability rates remain high, although potentially lower than in earlier estimates.[8] This 2008 longitudinal analysis showed estimates of 23% work disability at 1 to 3 years of disease onset and of 35% within 10 years.[8]

Clinical studies have shown better clinical outcomes when aggressive treatment is initiated early, including treatment with a wide range of disease-modifying antirheumatic drugs (DMARDs) and non-DMARD combination therapies.[7-9] A recent joint collaboration of the American College of Rheumatology (ACR) and the European League Against Rheumatism has led to the development of an updated classification system of RA, to shift the focus from late-stage disease features—such as structural changes and joint damage that can be determined from various imaging techniques—to early-stage disease features that are associated with persistent disease.[6] Given the advances in treatment for RA, including nonbiologic and biologic options, along with the

associated improved outcomes, this classification system update to include early-disease features marked a major shift in the RA disease construct.[6]

The ACR guidelines outline clinical treatment pathways by first defining disease duration and activity.[7] Disease duration is divided into 3 major categories: <6 months (equivalent to early disease), 6 to 24 months (equivalent to intermediate disease duration), and >24 months (equivalent to longer disease duration).[7] Disease activity measurements are often qualitative in early-stage disease, and measures are subject to clinical judgment.[7]

Pharmacotherapy for RA often includes a nonsteroidal antiinflammatory drug, selected use of glucocorticoids, and initiation of a DMARD early in the disease course.[1,7] Biologic therapies may be added when adequate disease control has not been met by previously initiated drug therapies, which may occur within the first year of diagnosis.[1,7] With regard to biologic therapies, the ACR further subdivides “early disease” by disease duration of <3 months or 3 to 6 months, to accommodate the needs for early advancement of the patient to biologic therapies when disease activity is high.[7]

Despite positive clinical outcomes from treatment advances, healthcare costs associated with the treatment of a prevalent and lifelong disease such as RA are a considerable issue for health plans. The ACR estimates that per-patient treatment with biologic therapies is typically in excess of $12,000 annually.[10] The Agency for Healthcare Research and Quality estimates the annual costs for RA medications from as low as a few hundred dollars for oral, nonbiologic DMARDs to a high of more than $16,000 for injectable biologic DMARDs.[11] As new therapeutic options for RA become available, provider practices and payer strategies to support evidence-based care within the confines of cost management demand close examination.

This study was conducted to identify provider and payer practices and perceptions regarding therapeutic options and reimbursement for RA. To this end, Reimbursement Intelligence, a healthcare research company, conducted parallel online surveys with health plan payers and rheumatologists. Payers were asked to also consider market trends and potential for formulary coverage of RA therapies currently in development.

Methods

Online parallel-structure surveys were conducted in November 2011 and were completed by 2 groups: 100 rheumatologists and 50 payers identified as advisors to Pharmacy & Therapeutics Committees who are formulary decision makers for RA coverage. The payer group survey respondents included 50 pharmacy and medical directors from national

years. The payer group of health plans represented 80 million covered lives.

The distribution of plan types among payer respondents included Medicare Part D, commercial plans, Medicare Advantage, freestanding prescription drug plans, Managed Medicaid, and dual-eligible populations. More than two thirds (69%) of payers represented commercial plans with 3- or 4-tier formularies.

Table 1

Table 1 Biologic Medications Indicated for Rheumatoid Arthritis

Brand name	Generic name
Actemra	Tocilizumab
Cimzia	Certolizumab
Enbrel	Etanercept
Humira	Adalimumab
Orencia	Abatacept
Simponi	Golimumab
Rituxan	Rituximab
Remicade	Infliximab

The rheumatologist group represented providers from large and small group practices, and ones with and without in-office infusion capabilities. Rheumatologists were screened as to whether their practice offered in-office biologic infusions, the practice volume of in-office infusions weekly, and the number of rheumatologists in the practice. The sample was weighted toward rheumatology and multispecialty group practices seeing more than 80 patients with RA monthly.

The parallel-structure payer and rheumatologist surveys were comprised of approximately 150 questions, and the survey instrument required answers to all questions. Survey questions included specific probes about 8 biologic therapies currently indicated for RA (**Table 1**); existing medications that may receive an RA indication; and new, small-molecule oral agents still in development. All respondents received an honorarium for their participation.

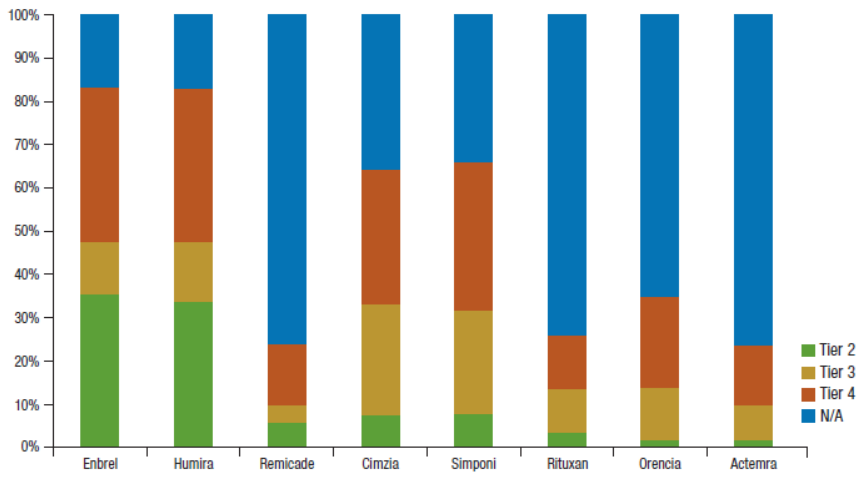
Results

Tier Placement

Figure 1

Figure 1 Payer Formulary Tier Placement for RA Biologics

Question to payers (N = 50): For the following agents covered under your pharmacy benefit, please select the corresponding tier positioning.



N/A indicates not applicable; RA, rheumatoid arthritis.

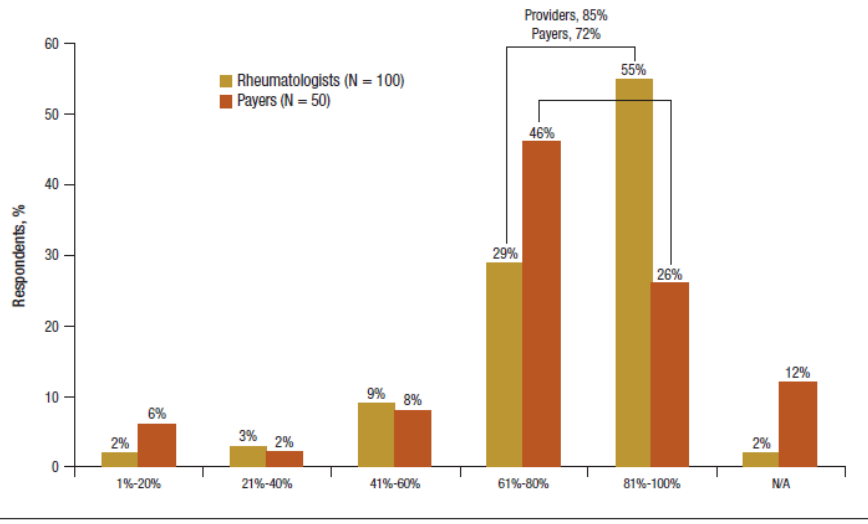
Tiered cost-sharing is a common strategy for therapies covered under a pharmacy benefit. Payers reported that none of the current 8 biologic medications (**Table 1**) covered under the pharmacy benefit is placed on tier 1. Tier 2 stat us was given most frequently to etanercept (Enbrel; 36%) and adalimumab (Humira; 34%), whereas the remaining products were distributed across tiers 3 and 4 (**Figure 1**).

Prior Authorizations and Step Edits

Figure 2

Figure 2 Approval Rates for Prior Authorization/Step Edits

Question: What is the approval rate for prior authorizations and step edits for your patients with RA?



N/A indicates not applicable; RA, rheumatoid arthritis.

To target medications to appropriate patients, health plans may require patients to meet predetermined clinical criteria and receive prior authorization before reimbursement is approved. Similarly, health plans

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.