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Golimumab Associated with Improved Patient-Reported Outcomes for RA, PsA, and AS

Washington, D.C.—Patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS) reported improved outcomes after treatment with golimumab, according to the non-interventional, prospective GO-NICE study presented by **Klaus Krüger, MD**, of the Praxiszentrum St. Bonifatius in München, Germany, and colleagues at the 2016 American College of Rheumatology Annual Meeting.

The study included 1613 patients who were enrolled from 158 sites in Germany. The authors assessed Disease Activity Score 28, Psoriatic Arthritis Response Criteria, Bath Ankylosing Spondylitis Disease Activity Index, quality of life, fatigue, sick days, quality of work, and safety outcomes related to golimumab treatment.

A total of 1458 patients (90.4%) had a baseline assessment and at least one additional visit and were included in the final analysis. See **TABLE 1** for baseline characteristics. After 24 months, 44.9% of those with RA, 54.6% of those with PsA, and 59.2% of those with AS had completed the study and were still receiving golimumab.

TABLE 1. Baseline Characteristics

Rheumatoid Arthritis (n=474)	
Mean age	54.9 years
Percent female	72.8%
Biologic-naïve	64.7%
Psoriatic Arthritis (n=501)	
Mean age	50.5 years
Percent female	54.1%
Biologic-naïve	56.5%
Ankylosing Spondylitis (n=483)	
Mean age	43.6 years
Percent female	33.5%
Biologic-naïve	61%

Quality of life (using EQ-5D-3L) was improved after six months of treatment and was maintained over 24 months. See **TABLE 2** for all outcomes.

During the two-year assessment period, the proportion of patients who required hospitalization decreased

TABLE 2. Comparison of Baseline versus Post-Treatment Patient-Reported Outcomes

	Baseline	24 Weeks after Treatment with Golimumab
Rheumatoid Arthritis		
Health state (per EQ-VAS)	51	63.4
Functional ability (per FFbH; <i>P</i> <.0001)	68.2	76.1
Mean FACIT-Fatigue score (<i>P</i> <.0001)	32.4	38.3
Number of work absenteeism days in the last six months	16.2	4.1
Number of reduced productivity days in the last six months	64.5	23.1
Disease impact on quality of work in the last six months (determined by 0=no impact; 10=very severe impact)	4.8	2.4
Psoriatic Arthritis		
Health state (per EQ-VAS)	48.4	64.3
Functional ability (per FFbH; <i>P</i> <.0001)	69	76.8
Mean FACIT-Fatigue score (<i>P</i> <.0001)	30	35.9
Number of work absenteeism days in the last six months	10.6	2
Number of reduced productivity days in the last six months	66.6	19.8
Disease impact on quality of work in the last six months (determined by 0=no impact; 10=very severe impact)	4.8	2.2
Ankylosing Spondylitis		
Health state (per EQ-VAS)	46.8	66.5
Functional ability (per FFbH; <i>P</i> <.0001)	69	78.5
Mean FACIT-Fatigue score (<i>P</i> <.0001)	29.9	37.9
Number of work absenteeism days in the last six months	14.7	3.9
Number of reduced productivity days in the last six months	66.3	17.3
Disease impact on quality of work in the last six months (determined by 0=no impact; 10=very severe impact)	4.8	2

EQ-VAS=EuroQoL-Visual Analogue Scale; FFbH=Hannover Functional Assessment; FACIT=Functional Assessment of Chronic Illness Therapy.

from 10.6% to 1.6%, while physiotherapy dropped from 28.8% to 16.6% and massage treatment decreased from 10.9% to 6.4%.

No new safety issues were reported. Four deaths occurred, three of which were not related to treatment with golimumab and the other was “unlikely related” to golimumab.

“Golimumab was an effective treatment in patients with RA, PsA, and AS in a real-life setting,” the authors concluded. “Treatment with golimumab showed remarkable improvements in clinical effectiveness, patient-reported quality of life parameters, and socio- and health-economic [parameters].”

REFERENCE

Krüger K, Burmester GR, Wassenberg S, et al. Golimumab improves patient-reported outcomes and socio- and health-economic parameters in patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS): Results from a non-interventional clinical evaluation in Germany. Abstract #629. Presented at the 2016 ACR/ARHP Annual Meeting, Washington, D.C., November 13, 2016.

Above-Level Dosing with Etanercept and Adalimumab Resulted in Increased Costs for Patients with Psoriatic Arthritis

Washington, D.C.—For patients with moderate-to-severe psoriatic arthritis (PsA), above-label dosing of a biologic medication may be necessary to achieve disease control. A study assessed health care costs associated with above-label dosing for etanercept (ETA), adalimumab (ADA), and golimumab (GOL), and found that ETA and ADA showed increased costs in annual mean total all-cause health care costs per patient. **Sergio Schwartzman, MD**, of the Hospital for Special Surgery in New York, NY, and colleagues presented their findings at the 2016 American College of Rheumatology Annual Meeting.

Adult patients with PsA were identified via the MarketScan® Commercial Claims database. Patients with data available between January 1, 2011, and March 31,

2013, were included and followed for one year, with a three-month look-forward period (post-index) ending on March 31, 2015. Patients were eligible for inclusion if they had ≥1 PsA diagnosis per the *International Classification of Diseases, 9th Revision* and ≥1 pharmacy claim for ETA, ADA, certolizumab (CER), GOL, or ustekinumab (UST). Patients receiving CER and UST were eventually excluded due to limited sample sizes (n=0 and n=14, respectively). Patients were excluded if they received intravenous therapy, switched to a different biologic following the use of the initial biologic, or had any autoimmune disease for which one of the studied biologics could potentially be used for treatment.

A total of 4245 patients with PsA were included, of whom 2342 received ETA, 1788 received ADA, and 115 received GOL.

Above-label use was defined as a daily maintenance dose ≥10% higher than indicated on the drug’s label. Health care costs were examined at <30 days, between 30 and 179 days, and at ≥180 days. Most patients had data available for ≥30 days of above-label use (90% for ETA, 85% for ADA, and 96% for GOL).

Above-label ETA and ADA use resulted in increased costs, while the observations for patients treated with GOL were limited by the small sample size. See **TABLE** for associated health care costs.

“Even a short duration of above-label dosing was associated with increased total health care costs among PsA patients treated with ETA and ADA,” the authors concluded.

REFERENCE

Schwartzman S, Li Y, Zhou H, et al. Economic impact of above-label dosing with biologics in patients with moderate-to-severe psoriatic arthritis. Abstract #2234. Presented at the 2016 ACR/ARHP Annual Meeting, Washington, D.C., November 15, 2016.

TABLE. Total Health Care Costs in Post-Index Period (Mean)

	<30 days above-label use			30-179 days above-label use			≥180 days above-label use		
	ETA (n=2118)	ADA (n=1520)	GOL (n=110)	ETA (n=129)	ADA (n=97)	GOL (n=2)	ETA (n=95)	ADA (n=171)	GOL (n=3)
All-cause	\$30,625	\$31,620	\$37,224	\$35,602	\$38,915	\$64,349	\$55,359	\$54,176	\$47,993
PsA-specific	\$23,246	\$24,411	\$26,155	\$27,533	\$26,911	\$46,607	\$44,827	\$45,289	\$44,533
Biologic	\$22,812	\$23,919	\$25,381	\$27,104	\$26,331	\$46,019	\$44,282	\$44,854	\$44,334
Non-Biologic	\$7814	\$7701	\$11,843	\$8498	\$12,584	\$18,330	\$11,076	\$9323	\$3658

ETA=etanercept; ADA=adalimumab; GOL=golimumab; PsA=psoriatic arthritis.

Clinical Assessment Plus Biologic Drug Monitoring Has Potential for Adalimumab Tapering in Patients with RA, PsA, and AS

Washington, D.C.—The usual practice for adalimumab dose tapering includes clinical assessment, especially in patients who have achieved clinical remission. An ongoing study assessed a more personalized approach to dose tapering that included biological drug monitoring (BDM; intervention group) in patients with moderate-to-severe rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS) and found that clinical assessment plus BDM was more effective than clinical assessment alone (control group). **Iñigo Gorostiza, BSc, MS**, of the research department at the Hospital Universitario de Basurto in Bilbao, Spain, and colleagues presented the partial descriptive data at the 2016 American College of Rheumatology Annual Meeting. Follow-up data were expected at a later date to reflect annual direct costs and quality-adjusted life years associated with the intervention.

This prospective, multicenter, intervention study included adult patients with RA, PsA, and AS who were clinically stable for at least six months. Patients were recruited from three sites in Spain. All patients were treated with 40 mg of subcutaneous adalimumab, with treatment frequency adjusted based on physician criteria. Patients were assessed at eight different visits for up to 18 months.

A total of 169 patients were included:

- RA: 30 interventions, 33 controls
- PsA: 33 interventions, 21 controls
- AS: 46 interventions, 6 controls

The median disease duration was 117 months for RA, 98.5 months for PsA, and 101.5 months for AS. In the control cohort, 10 patients (16.7%) had low disease activity and 50 (83.3%) were in remission compared with 29 (26.6%) and 80 (73.4%) patients in the intervention group, respectively.

Median trough adalimumab levels (measured with Promonitor-ADL and Promonitor-ANTI-ADL) were 5.5 mg/L in the control group and 5.3 mg/L in the intervention group, and at week 34, median trough levels were 5.2 mg/L and 5.5 mg/L, respectively.

Among the 117 patients who were in remission at base-

line, 69.6% of the control group (n=32/46) and 76.1% of the intervention group (n=54/71) remained in remission at 34 weeks. Among the 35 patients who had low disease activity at baseline, 28.6% in the control group (n=2/7) and 34.7% in the intervention group (n=10/28) were in remission at 34 weeks.

“Partial descriptive data point toward a positive effect of BDM-complemented management compared [with] conventional practice only,” the authors concluded.

REFERENCE

Gorostiza I, Angulo EU, Arango CG, et al. Prospective, intervention, multicenter study of utility of biologic drug monitoring with respect to the efficacy and cost of adalimumab tapering in patients with rheumatic diseases (34-week descriptive data). Abstract #636. Presented at the 2016 ACR/ARHP Annual Meeting, Washington, D.C., November 13, 2016.

Sarilumab Superior to Adalimumab for Patients with Active RA Who Are Intolerant to Methotrexate

Washington, D.C.—In a double-blind, randomized, double-dummy, phase 3 safety and efficacy trial comparing the use of sarilumab versus adalimumab in patients with active rheumatoid arthritis (RA) with an intolerant or inadequate response to methotrexate, sarilumab demonstrated superiority. **Gerd-Rüdiger Burmester, PhD, MD**, of the Rheumatologie und Klinische Immunologie der Charité-Universitätsmedizin in Berlin, Germany, and colleagues presented the study's findings at the 2016 American College of Rheumatology Annual Meeting.

A total of 369 adult patients were included in the study and received:

- Sarilumab 200 mg administered subcutaneously every two weeks (n=184)
- Adalimumab 40 mg administered subcutaneously every two weeks (n=185)

At 16 weeks, patients who did not respond could increase to weekly adalimumab treatment (or matching placebo). The study's primary end point was change in Disease Activity Score 28-Erythrocyte Sedimentation Rate (DAS28-ESR) from baseline to week 24, while the secondary end point was Clinical Disease Activity Index (CDAI). Baseline characteristics were similar between treatment arms.

TABLE. Efficacy Outcomes for Sarilumab versus Adalimumab at 24 Weeks*

	Sarilumab 200 mg [†] (n=184)	Adalimumab 40 mg [†] (n=185)	P value
DAS28-ESR mean	3.5	4.5	<.0001
LS mean change from baseline	-3.3	-2.2	<.0001
DAS28-ESR remission	49 (26.6%)	13 (7%)	<.0001
ACR20 response	132 (71.7%)	108 (58.4%)	.0074
ACR50 response	84 (45.7%)	55 (29.7%)	.0017
ACR70 response	43 (23.4%)	22 (11.9%)	.0036
HAQ-DI mean	1	1.2	.0074
LS mean change from baseline	-0.6	-0.4	.0037
CDAI mean	13.8	16.6	.0244
LS mean change from baseline	-28.9	-25.2	.0013
CDAI remission	13 (7.1%)	5 (2.7%)	.0468

*This includes patients switching to weekly adalimumab.

[†]Administered every two weeks.

DAS=Disease Activity Score; ESR=Erythrocyte Sedimentation Rate; LS=least squares; ACR=American College of Rheumatology 20/50/70 responses; HAQ-DI=Health Assessment Questionnaire-Disability Index; CDAI=Clinical Disease Activity Index.

After 24 weeks, patients treated with sarilumab had significantly greater decrease in DAS28-ESR scores, greater incidence of DAS28-ESR remission and American College of Rheumatology 20/50/70 responses, and improvement in Health Assessment Questionnaire-Disability Index. See **TABLE** for complete results.

Patients treated with sarilumab were twice as likely to achieve CDAI remission at week 24 compared with the adalimumab cohort ($P<.05$)

The incidence of adverse events (AEs; 64%) and serious AEs (sarilumab=5% vs adalimumab=7%) were similar between groups. The most common AEs associated with sarilumab included neutropenia and injection site reactions, while headache and worsening RA were most common with adalimumab. Infections occurred in 29% of patients treated with sarilumab compared with 28% treated with adalimumab. Neutropenia was not associated with an increased incidence of infections, according to the study. Most injection site reactions were mild, with two cases leading to treatment discontinuation in the sarilumab group. One death related to acute cardiac failure occurred in the sarilumab cohort 35 days after the patient initiated treatment.

Patients treated with sarilumab were twice as likely to achieve Clinical Disease Activity Index remission at week 24 compared with the adalimumab cohort.

“Sarilumab monotherapy demonstrated superiority to adalimumab monotherapy in reduction of disease activity and improvement in signs and symptoms and physical function in patients with active RA who were inappropriate candidates for continued treatment with methotrexate due to intolerance or inadequate response,” the authors concluded.

REFERENCE

Burmester GR, Lin Y, Patel R, et al. Efficacy and safety of sarilumab versus adalimumab in a phase 3, randomized, double-blind, monotherapy study in patients with active rheumatoid arthritis with intolerance or inadequate response to methotrexate. Abstract #3221. Presented at the 2016 ACR/ARHP Annual Meeting, Washington, D.C., November 16, 2016.

Patients with ACPA-Positive RA Incur Higher Economic Costs

Washington, D.C.—Patients with rheumatoid arthritis (RA) who have anti-citrullinated protein antibodies (ACPA) usually have more severe disease and joint damage. According to a study presented by **Jason Shafrin, PhD**, of Precision Health Economics in Los Angeles, CA, and colleagues at the 2016 American College of Rheumatology Annual Meeting, patients with ACPA-positive RA incur \$2697 additional annual RA-associated costs compared with those who are ACPA-negative (\$7940 vs \$5243; $P=.002$).

The authors used insurance claims from IMS PharMetrics Plus and electronic medical record (EMR) data from 2010 to 2015 to identify 647,171 adult patients with incident RA (defined as those who had no claims with an RA diagnosis in the six months prior to first observed RA diagnosis). Inclusion criteria were having ≥ 1 inpatient or ≥ 2 outpatient claims for RA, per the *International Classification of Disease, 9th Revision*, as well as an anti-cyclic citrullinated peptide (anti-CCP) antibody test within six months of diagnosis.

The primary outcome was RA-related medical expenditure (defined as the sum of payer- and patient-paid amounts of all claims with an RA diagnosis code). Secondary outcomes included health care utilization metrics, such as treatment with a disease-modifying anti-rheumatic drug (DMARD) and physician visits.

A total of 89,296 patients met the inclusion criteria and 42,285 (47%) had an anti-CCP test. Of those, 9747 had EMR data available, and 859 patients had ACPA test results. Twenty-five percent of patients ($n=212$) were ACPA-positive, and 26% were male ($n=219$).

TABLE. Economic Burden of Patients with RA by ACPA Status

Annual RA-Associated Costs	RA with ACPA	RA without ACPA
Prescriptions*	\$3560	\$1816
Medical expenditures†	\$4380	\$3427
Medical inpatient	\$1292	\$1680
Medical outpatient*	\$3089	\$1746
Total*	\$7940	\$5243

* $P<.05$

†Excluding prescription drug costs ($P=.168$)

RA=rheumatoid arthritis; ACPA=anti-citrullinated protein antibodies.

ACPA-positive patients were more likely to use either conventional (71.2% vs 49.6%, respectively; $P<.001$) or biologic (20.3% vs 11.8%, respectively; $P<.001$) DMARDs during the first year after diagnosis compared with ACPA-negative patients. Patients with ACPA also had more physician visits (5.57 vs 3.91 times per year, respectively; $P<.001$).

See **TABLE** for economic outcomes for those with and without ACPA.

“Patients with RA who are ACPA-positive have a higher RA-related economic burden than patients who are ACPA-negative,” the authors concluded. “Providers may consider utilizing the results of anti-CCP testing to inform treatment decisions in this higher-cost population.”

REFERENCE

Shafrin J, Hou N, Tebeka MG, et al. Economic burden of rheumatoid arthritis is higher for ACPA-positive patients. Abstract #2229. Presented at the 2016 ACR/ARHP Annual Meeting, Washington, D.C., November 15, 2016.

Dermatomyositis and Polymyositis Contribute High Health Care and Work Loss Costs in the United States

Washington, D.C.—Dermatomyositis (DM) and polymyositis (PM) are inflammatory myopathies that lead to muscle weakness and disability and result in significant health care resource utilization and work loss among patients. According to a study presented by **J. Bradford Rice, PhD**, of the Analysis Group, Inc., in Boston, MA, and colleagues at the 2016 American College of Rheumatology Annual Meeting, DM/PM imposes a total direct medical cost burden of approximately \$457 million to \$602 million (in 2013 U.S. dollars) to commercial payers.

The study included 2587 patients who were 18 to 64 years of age and diagnosed with DM/PM between January 1, 1998, and March 31, 2014. Patients were selected from OptumHealth Reporting and Insights, a large, de-identified, privately-insured administrative claims database. Patients were matched 1:1 with non-DM/PM controls from the same database.

The authors assessed health care costs, including inpatient and outpatient, emergency department, pharmacy, and other use, as well as indirect work loss, including disability days and medically-related absenteeism, over a

12-month period following diagnosis. The authors estimated that DM/PM prevalence ranges from 14.8 to 19.5 cases per 100,000 persons, per recent findings in the literature.

Over 12 months, commercial payers incurred \$23,064 in total health care costs per DM/PM patient, which was 47% (\$7368) higher compared with the control cohort (\$15,695; $P < .001$).

Patients with DM/PM incur \$146 million to \$192 million in excess costs compared with the matched controls.

In addition, work loss among DM/PM patients amounted to \$3621 annually, which was \$633 (21%) more than the control cohort (\$2988; $P < .001$). The study suggested that patients with DM/PM impose an indirect cost burden of \$76 million to \$100 million to employers in work-loss costs, which was in excess of \$13 million to \$17 million compared with the control group.

Thus, the estimated total annual health care costs (direct and indirect) of DM/PM range from \$533 million to \$702 million.

“DM/PM is associated with substantial economic burden in the U.S. population due to significantly increased health care costs and work loss,” the authors concluded. “Moreover, results of this analysis potentially underestimate the excess burden of DM/PM because a few high-cost patients could not be matched. Also, the actual national cost of DM/PM is likely understated, as this study excluded individuals ≥ 65 years of age, out-of-pocket costs, supplemental insurer payments, and informal caregiving. Finally, only costs in the 12 months following diagnosis were assessed; costs may increase due to changes in disease severity over time.”

REFERENCE

Bradford Rice J, White A, Galebach P, et al. The economic burden of dermatomyositis and polymyositis in the US. Abstract #1237. Presented at the 2016 ACR/ARHP Annual Meeting, Washington, D.C., November 14, 2016.

Investigational Drug CC-292 Fails Primary End Point Compared with Placebo in Patients with Active RA

Washington, D.C.—The investigational drug CC-292 is a small molecule Bruton’s tyrosine kinase (BTK) inhibitor that may help regulate inflammation related to rheumatoid arthritis (RA). However, in a study presented by **Alan J. Kivitz, MD**, of Altoona Arthritis & Osteo Center in Duncansville, PA, and colleagues at the 2016 American

College of Rheumatology Annual Meeting, the drug did not meet its primary end point of improvement in American College of Rheumatology (ACR) 20 at four weeks compared with placebo.

The double-blind, proof-of-concept, phase 2a safety and efficacy study enrolled 47 adult female RA patients who were randomized 1:1 to receive CC-292 375 mg administered orally daily or placebo. Eligibility criteria included a diagnosis of sero-positive RA for at least six months and meeting the 2010 ACR/European League Against Rheumatism Classification Criteria for RA. Patients had active RA despite at least three months of treatment with methotrexate on a stable dose (7.5-25 mg/week oral or parenteral) for at least four weeks prior to randomization. Patients could concomitantly receive sulfasalazine, anti-malarials, and low-dose corticosteroids (including prednisone or equivalent ≤ 10 mg/day).

CC-292 resulted in ACR20 improvement in 42% of patients ($n=10/24$) compared with 22% in the placebo cohort ($n=5/23$). ACR20 improvement separated from placebo as early as week one and progressed through week four, though this trend was not considered statistically significant ($P=.25$).

CC-292 also did not statistically improve Disease Activity Score 28, Health Assessment Questionnaire-Disability Index, or swollen and tender joint counts.

CC-292 did reduce osteoclast activity, B-cell lymph node trafficking, and class switched and activated memory B-cell, while increasing mature naïve B cells.

Treatment-related adverse events (AEs) were similar between treatment arms, with the most frequent ($\geq 5\%$) AEs related to CC-292 including nausea, back pain, diarrhea, cough, and migraine. No deaths were reported.

“The study did not meet its primary end point of improvement in ACR20 at four weeks, nor the secondary end points of ACR50 and ACR70 at four weeks, although there were numerical trends combined with a responder subgroup analysis suggesting potential efficacy of CC-292 in this female RA population,” the authors concluded. “In this study, CC-292 was well-tolerated and had a favorable safety profile over four weeks of treatment. CC-292 BTK inhibition impacts RA with a different mechanism of action and profile than current therapies.”

REFERENCE

Kivitz AJ, Gupta R, Valenzuela G, et al. A phase 2a, 4-week double-blind, proof-of-concept efficacy and safety study of CC-292 versus placebo as co-therapy with methotrexate in active rheumatoid arthritis (RA). Abstract #1587. Presented at the 2016 ACR/ARHP Annual Meeting, Washington, D.C., November 14, 2016.

After Inadequate Treatment with TNFi, Switching to New MOA is More Cost-Effective than Cycling to Another TNFi

Washington, D.C.—Patients with rheumatoid arthritis (RA) who do not have an adequate response to a tumor necrosis factor inhibitor (TNFi) can switch to another disease-modifying anti-rheumatic drug (DMARD) either by cycling to another TNFi or switching to a new mechanism of action (MOA). A study presented by **Machaon Bonafede, PhD, MPH**, of Truven Health Analytics in Cambridge, MA, and colleagues at the 2016 American College of Rheumatology Annual Meeting assessed the cost-effectiveness of these

two treatment strategies and found that switching to a new MOA was more effective and less costly than cycling to another TNFi.

The claims-based analysis used data from 8517 patients with RA in the Truven Health Analytics MarketScan® Commercial database. Patients either cycled from one TNFi to another (n=5997; including adalimumab, certolizumab pegol, etanercept, golimumab, or infliximab) or switched to a new MOA (n=2520) biologic (including abatacept or tocilizumab) or targeted oral DMARD (tofacitinib) between January 2010 and December 2014.

An algorithm was applied to estimate treatment effectiveness during the 12 months post-switch based on the following six criteria:

1. ≥80% adherence
2. No dose increase
3. No addition of a synthetic DMARD (including leflunomide, methotrexate, sulfasalazine, or hydroxychloroquine)
4. No switch to another targeted DMARD
5. No new/increased oral glucocorticoid
6. Intra-articular injections on <2 days

TABLE. 12-Month Post-Switch Outcomes

	TNFi Cyclers (n=5997)	New MOA Switchers (n=2520)	Difference*	P Value
Average targeted DMARD costs	\$38,456	\$33,008	-\$5448	<.001
Effectiveness per claims-based algorithm				
Overall	23.3%	26%	2.7%	.008
Adherence	39.1%	39.8%	0.7%	.56
No dose increase	88%	93.9%	5.9%	<.001
No new conventional synthetic DMARD	85%	85.7%	0.8%	0.371
No switch to another targeted DMARD	64.2%	69.6%	5.4%	<.001
No increased/new glucocorticoids	85.9%	85.3%	-0.6%	.451
Intra-articular injections on <2 days	90.6%	90.6%	0%	.973
Drug cost per effectively treated patient				
Overall	\$165,200	\$126,991	-\$38,208	N/A
Adherence	\$98,387	\$83,013	-\$15,373	N/A
No dose increase	\$43,694	\$35,156	-\$8538	N/A
No new conventional synthetic DMARD	\$45,264	\$38,509	-\$6755	N/A
No switch to another targeted DMARD	\$59,917	\$47,423	-\$12,494	N/A
No increased/new glucocorticoids	\$44,746	\$38,688	-\$6058	N/A
Intra-articular injections on <2 days	\$42,456	\$36,450	-\$6005	N/A

*New MOA switchers versus TNFi cyclist. TNFi=tumor necrosis factor inhibitor; MOA=mechanism of action; DMARD=disease-modifying anti-rheumatic drug; N/A=not applicable.

Costs were calculated from health care claims based on the paid amount for targeted DMARDs and adjusted for inflation according to price changes for each drug during the study period. Cost per effectively treated patient was defined as the average 12-month post-switching cost per patient for targeted DMARDs, divided by the proportion

of patients categorized by the algorithm as being treated effectively.

Patients were similar in the intervention and control groups according to age (mean = 49.7 vs 51 years, respectively), sex (female = 81.2% vs 83.9%, respectively), and comorbidity (mean Deyo-Charlson index score = 1.4 vs 1.5, respectively).

The authors found that costs and treatment effectiveness favored MOA switching over TNFi cycling. See **TABLE** on page 8 for outcomes.

“After prior exposure to TNFi, switching to a new MOA rather than cycling to another TNFi was associated with better treatment effectiveness and lower drug costs, resulting in lower cost per effectively treated patient,” the authors concluded.

REFERENCE

Bonafede M, Wei W, Chen CI, et al. Claims-based analysis of cost-effectiveness among patients with rheumatoid arthritis who switched from a tumor necrosis factor inhibitor to another targeted disease-modifying antirheumatic drug. Abstract #1999. Presented at the 2016 ACR/ARHP Annual Meeting, Washington, D.C., November 14, 2016.

Intravenous versus Subcutaneous Administration of Abatacept for RA

Washington, D.C.—Using real-world data, **Christopher J. Swearingen, PhD**, of the Department of Medicine in the Division of Rheumatology at New York University School of Medicine in New York, NY, and colleagues assessed outcomes for intravenous versus subcutaneous administration of abatacept in patients with rheumatoid arthritis (RA) and found no difference in efficacy, though the subcutaneous cohort was less likely to follow-up. The findings were presented at the 2016 American College of Rheumatology Annual Meeting.

TABLE. Follow-Up Outcomes Related to Abatacept Route of Administration

	Intravenous Abatacept	Subcutaneous Abatacept	P value
Number of follow-ups	13.3	2.5	<.001
Clinical response	42 (32.6%)	4 (5.9%)	<.001
Time to response	6 months	5.8 months	.96

There are no major differences in efficacy of the different administration routes of abatacept in time to response when treating rheumatoid arthritis patients.

The authors used data from the Arthritis Registry Monitoring Database, which has been collecting prospective data since 2005 for all patients receiving routine care. Each patient in this setting completes a two-sided, one-page Multidimensional Health Assessment Questionnaire at every visit, which includes scales for physical function, pain, patient global estimate (PATGL), fatigue, and a self-report Rheumatoid Arthritis Disease Activity Index painful joint count.

In this preliminary study, the authors examined self-reported disease activity and time to first response (defined as at least a 3.6 improvement in routine assessment of patient index data 3 [RAPID3] severity).

A total of 2168 patients were reviewed and 198 were included in this analysis, with an average of 10.9 follow-up encounters. The mean patient age was 53 years, 89% were female (n=177), and the average baseline RAPID3 severity was 14.5. Intravenous abatacept was administered in 154 patients, while 44 received subcutaneous abatacept.

PATGL was slightly higher in the subcutaneous cohort, but the overall RAPID3 severity was not different. Patients in the subcutaneous cohort were less likely to follow-up, but despite this, the average time to clinical response was approximately six months in each group. See **TABLE** for follow-up outcomes related to route of administration.

“Our data suggest that there are no major differences in efficacy of the different administration routes of abatacept in time to response when treating RA patients,” the authors concluded. “Further investigation into previous treatment history to determine refractory status and its impact on abatacept efficacy is warranted.” ■

REFERENCE

Swearingen CJ, Poon J, Bernstein H, and Yazici Y. Comparison of intravenous versus subcutaneous abatacept for the treatment of rheumatoid arthritis in a routine clinical care setting: A preliminary, time to response analysis. Abstract #2538. Presented at the 2016 ACR/ARHP Annual Meeting, Washington, D.C., November 15, 2016.



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