Benefit-risk Analysis of Adalimumab and Alternative Treatments for Moderate to Severe Rheumatoid Arthritis

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Background
Rheumatoid arthritis (RA) is a chronic disease characterized by inflammation of the lining or synovium of the joints and leading to long-term joint damage resulting in chronic pain, loss of function, and disability.

Objectives
To compare treatment-related risks and improvements in outcomes in terms of net health benefit (NHB) for 3 treatments for moderate to severe RA:
– MTX alone.
– ADA in combination with MTX, and
– IFX in combination with MTX.

Methods
Benefit-Risk Model
An individual-level simulation model was developed in which a cohort of patients with RA initiating treatment progressed at 6-month intervals for 10 years or until withdrawal from therapy.

Patient Populations
Patients with moderate or high RA benefited and risks were compared for different treatments for RA are limited.

RA Therapies
Patients observed under each of 3 treatment regimens for RA (Table 1).

Study Populations
The baseline model was run for 15,000 individuals from the MTX-naïve and IFX-naïve populations.

Patient Populations
– MTX-naïve: patients with high level of RA disease activity who did not receive previous treatment with DMARDs.
– IFX-naïve: patients with moderate or high RA disease severity who did not respond to DMARDs.

Benefits
– Measured response at the end of therapy
  – ACR20, ACR50, ACR70

Risks
– Withdrawal due to lack of efficacy (LOE).

Outcomes
– Average years on therapy per patient
– Percent and numbers withdrawn from therapy total, due to LOE, due to death.

Results

Table 1. Characteristics of Study Populations

Table 2. Characteristics of Study Populations

Table 3. Predicted Outcomes Over 10 Years: MTX-Naïve Population

Table 4. Predicted Outcomes Over 10 Years: IFX-Naïve Population

Table 5. Predicted Outcomes Over 10 Years: DMARD-Failure Population

Table 6. Results of Incremental NHB in QALYs PP vs. ADA

Figure 1. Schematic Representation of Benefit-Risk Model

Figure 2. Percentage of Patients MTX-Naïve Population on Therapy Over Time

Figure 3. Distribution of Patients in the MTX-Naïve Population by Status Over Time

Figure 4. Percentage of Patients in the DMARD-Failure Population on Therapy Over Time

Figure 5. Distribution of Patients by Status Over Time in the DMARD-Failure Population

Figure 6. Percentage of Patients MTX-Naïve vs. ADA + MTX for the MTX-Naïve Population

Figure 7. Percentage of Patients MTX-Naïve vs. ADA + MTX for the IFX-Naïve Population

Figure 8. Percentage of Patients MTX-Naïve vs. ADA + MTX for the DMARD-Failure Population

Conclusions
To our knowledge, there are no published benefit-risk analyses comparing these RA treatments.

Analysis of treatment-related risks vs. improvements in outcomes in a simulation model revealed that both MTX-naïve and DMARD-naïve patients may experience greater net health benefits when treated with a combination of ADA and MTX than when treated with a combination of IFX + MTX or MTX alone.

References

PMSS

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