# Monitoring Abatacept Therapy

Evidence-based Medicine | Official Recommendations | Expert opinion

**Abatacept treatment monitoring** relies on clinical and laboratory data to assess the effectiveness and safety of the drug.

Since abatacept is given once a month after the first three infusions, regular clinical follow-up can be provided at each infusion (refer to the model letters for informing retailed rheumatologists and primary-care physicians). In the short-term, the risk of acute infusion- reactions should be assessed (refer to the "acute infusion- Reactions" fact sheet).

**Clinical and structural monitoring** evaluates the treatment response, using the DAS 28.

A treatment response is defined as follows:

- Improvement in the DAS 28 by at least 0.6 at week 16 (if this goal is not achieved, abatacept therapy can be stopped)
- and improvement in the DAS 28 of at least 1.2 (if possible with a DAS 28 no greater than 3.2) at week 24.

Subsequently, the patient should be evaluated at least once every 3 months to assess disease activity (DAS 28 or SDAI), quality of life, and laboratory markers for inflammation (ESR and/or CRP every 3 months) (refer to the model letter for informing retailed rheumatologists).

Structural damage progression should be evaluated (using radiographs of the hands and feet) after 1 year of abatacept therapy.

The response to abatacept was evaluated over a 6-month period in the AIM, ATTEST, ATTAIN, and ARRIVE trials. In patients who responded inadequately to TNF antagonist therapy and to methotrexate, abatacept significantly decreased disease activity. A clinically meaningful improvement (CMI) defined as a decrease of at least 1.2-point in DAS 28 change from baseline was statistically significantly in the abatacept group, as early as the first month, in the AIM and ATTEST studies. Overall the CMI rate at 3-month was on average 70% in the abatacept groups in the four studies. As the treatment response continues to develop over the first 6 months, the best period for evaluating the response to abatacept treatment is between the third and sixth month (1-3).

**Clinical and laboratory monitoring of safety of abatacept**

Safety should be assessed clinically at each abatacept infusion and whenever an unexpected event occurs.

As with all biotherapies, careful attention should be given to bacterial infections, (mainly in patients with COPD); to viral infections; and to symptoms that may suggest a solid cancer or hematological malignancy (refer to the "Bacterial and Viral Infections" and "Malignancies" fact sheets).

No specific laboratory or immunological tests are needed to monitor abatacept therapy. Laboratory tests for inflammation are required to calculate DAS, and the appropriate laboratory tests should be obtained to monitor concomitant treatments (e.g., methotrexate), according to standard practice.

Remember to perform the investigations required for concomitant medications (e.g., methotrexate). In the absence of specific problems, blood cell counts (leukopenia and thrombocytopenia are uncommon adverse events) and transaminase assays should be performed every 3 months.

**In women of childbearing potential,** an effective birth control method should be used throughout the treatment and for the first 14 weeks after treatment discontinuation.

Given the elimination half-life of abatacept, 97% of the drug is cleared from the body within 14 weeks of the last dose, assuming linear kinetics. Attempts to conceive may therefore be started 14 weeks after the last abatacept infusion (refer to the "Pregnancy" fact sheet).

**Practical situations:** pregnancy, vaccination, travel, surgery, and drug-drug interactions are discussed in specific fact sheets ("Pregnancy", "Vaccination", "Travel", "Surgery", and "Drug-Drug Interactions").