



Initial pre-treatment assessment

Evidence-based Medicine

Official Recommendations

Expert opinion

This checklist is designed to help you conduct a systematic search for contraindications to abatacept therapy. It does not include evaluations of disease activity and severity of RA to be treated with abatacept.

When interviewing the patient, check the absence of the following:

- A history of tuberculosis in the patient or family or contact with a tuberculosis patient
- A history of severe, chronic, and/or recurrent infections (bacterial, viral)
- A history of solid cancer
- A history of chronic obstructive pulmonary disease (COPD)
- A history of autoimmune disease

When conducting the physical examination of the patient, check the absence of the following:

- Fever
- Active infection
- Lymphadenopathy
- Evidence suggesting a malignancy
- Hypertension

Vaccinations:

- Boosters should be offered as appropriate, if possible at least 2 weeks before starting abatacept therapy
- Administration of the pneumococcal vaccine should be recommended

Investigations that should be obtained routinely at the first evaluation:

- Blood cell counts
- Serum protein electrophoresis
- Chest radiograph
- 5-IU tuberculin skin test or *in vitro* interferon gamma release assay (IGRA)
 - In patients with a history of prophylactic antituberculosis treatment given because a previous intradermal test showed an induration larger than 5 mm in diameter, the intradermal test does not need be repeated.
 - In patients who had a negative intradermal skin test when screened at least 1 year earlier, the test should be repeated.
 - In patients who have never been screened, national guidelines for detecting latent tuberculosis should be followed.
- Hepatitis B and C serology and, and HIV serology following patient consent. If tests done within the last 5 years are available, re-testing is unnecessary unless the patient has risk factors or a history of a high-risk medical procedure in the interval

- Standard practice should be followed regarding the detection of cancer.
 - Screening for colorectal cancer
 - Individual screening for prostate cancer
 - Screening mammography for breast cancer

The following investigations are recommended

- In patients previously treated with rituximab: lymphocyte typing and immunoglobulin assay by weight

Contraindications to abatacept therapy

- Hypersensitivity to abatacept or to any of its excipients
- Severe uncontrolled infection such as sepsis or opportunistic infection

Warnings when using abatacept

- Past History of recurrent or chronic infection or risk factors for infection
- Abatacept therapy should be stopped in case of severe infection
- History of tuberculosis or evidence of tuberculosis
- History of viral hepatitis
- Recent or scheduled vaccination
- Diabetes mellitus: abatacept therapy can interfere with blood glucose measurements by some devices (refer to the Summary of Product Characteristics)
- Monoclonal gammopathy of undetermined significance (MGUS) (refer to the fact sheet entitled "Lymphomas and other hematological diseases")
- Malignancy in the past 5 years other than skin cancer (except for melanoma and severe squamous cell carcinoma) removed completely with tumor-free margins