Model of information letter for the primary-care physician

....., on .....

Dear colleague,

You will soon receive a visit from Mr./Ms. ....., born on..... in whom we recently started treatment with a biologic agent.
In this patient, we decided to start abatacept therapy as part of the management for his/her rheumatoid arthritis.

What is abatacept?

Abatacept is a **fusion protein analogous to CTLA-4** and therefore inhibits the activation of T cells. Abatacept has been proven effective on the symptoms and destructive lesions associated with RA. These results prompted the healthcare authorities to grant abatacept a marketing authorization for RA, in 2007, in combination with methotrexate.

Your patient received abatacept as an intravenous infusion, in a dose of ....., in the department of ..... (Dr.....), on.....
The next infusion is scheduled to take place 14 days after the first infusion, in the same dose, and the third infusion 14 days after the second infusion. Thereafter, your patient will receive one infusion per month, in the same dose.

Abatacept was given in addition to your patient's usual treatment for RA, i.e., ...

What is known about the effectiveness of abatacept?

The effect of abatacept on the signs and symptoms of RA usually becomes apparent gradually over the first few months of the treatment. The final effectiveness evaluation is usually performed at the end of the sixth month.

What is known about the risks associated with abatacept therapy?

- A reaction to the molecule during the infusion or within the next few hours is a very rare event. Simple symptomatic treatment is usually sufficient. However, the development of constitutional symptoms, respiratory or cardiovascular manifestations, or diffuse skin lesions should lead to hospital admission on an emergency basis.
- Infections may occur in abatacept-treated patients. The most common infections are pneumonia and bronchitis, although cellulitis, acute pyelonephritis or other urinary tract

infections, diverticulitis, and other infections may develop. When there is no evidence of severe disease, appropriate antibiotic therapy should be given promptly. Patients with systemic manifestations or complications must be admitted immediately.

- The most common adverse events are nausea and headaches. Other adverse events are uncommon. The following have been reported: transaminase elevation, hypertension or hypotension, weight gain, tachycardia or bradycardia, thrombocytopenia, leukopenia. This non-exhaustive list should not distract from the very good overall safety profile of abatacept to date.

Practical considerations

- After the first three infusions, which occur over 1 month, an infusion is given once a month during a brief hospital stay (a few hours). The effectiveness and safety of the treatment should be assessed during a visit to the patient's usual rheumatologist, at least once every 3 months. However, your patient may ask to see you in the event of unusual symptoms, whose relation to abatacept will have to be assessed. If you are in any doubt, please contact a member of our team.
  - A rheumatologist visit is needed at least once every 3 months to assess effectiveness based on clinical data (Disease Activity Score, DAS) and laboratory tests (ESR-CRP).
  - We will work together to monitor safety. Given the concomitant use of methotrexate, blood cell counts and transaminase assays should be obtained every 3 months.
- Before the first infusion, we checked the immunization status of your patient.

  ❒ The following vaccine ..... was given on .....

  ❒ No vaccinations were considered necessary

  Vaccination or re-vaccination with a non-live vaccine (e.g., influenza) can be performed during abatacept therapy. Annual administration of the influenza vaccine is recommended. Live viral vaccines (oral polio, MMR, varicella, yellow fever) are contraindicated throughout abatacept therapy and for the first 3 months after abatacept discontinuation.
- In the current state of our knowledge, pregnancy is contraindicated until 14 weeks after the end of abatacept therapy.
- When a surgical procedure is scheduled, the time needed from the last abatacept infusion to surgery is 2 months. This interval may be adjusted based on the nature of the surgical procedure (because the risk of infection varies across procedures), patient-related factors (particularly the risk of infection in the individual patient), the severity of the rheumatic disease, and the degree of control achieved by the treatment.
- When emergent surgery is needed, the need for prophylactic antimicrobial therapy should be discussed on a case-by-case basis.
- For routine dental care (cavities, scaling), prophylactic antimicrobial therapy can be given, without changing the antirheumatic regimen. For dental procedures associated with a risk of infection (extraction, apical granuloma, abscess…), the next abatacept infusion should be postponed, as with surgical procedures, and prophylactic antimicrobial therapy offered.

- The patient may travel provided no live vaccines (yellow fever) are required. As with all travelers, measures aimed at preventing infections should be followed scrupulously. Antimalarial prophylaxis can be used.

Information was given to the patient before the abatacept infusion.

Please let us know about any events that you feel are unusual. We will be happy to provide any additional information you may need.

Sincerely,

cachet du médecin

Physician in charge:
Dr. .....
Telephone: .....
Physician's stamp