Guselkumab

Instructions for use

Table 1: Instructions for use (Guselkumab)

Pre-treatment

100 % Agreement [1]

- Physicians are encouraged to enroll their patients in a registry (if available)
- Objective assessment of the disease (such as PASI/BSA/PGA; arthritis)
- HRQoL (such as DLQI, Skindex-29 or 17)
- Medical history and physical examination including prior exposure to treatments, malignancies, infections
- Recommended measures include:
    - Check for skin cancer
    - Check for lymphadenopathy
    - Laboratory parameters (see **Table 2**)
    - Exclusion of tuberculosis (see chapter: " tuberculosis")
    - Check for evidence of active infection
    - Check need for vaccines
- Reliable contraception

During treatment

- Objective assessment of the disease (such as PASI/BSA/PGA; arthritis)
- HRQoL (such as DLQI, Skindex-29 or 17)
- Laboratory controls (see **Table 2**)
- Medical history and physical examination including infections, including monitoring signs and symptoms of tuberculosis
- Reliable contraception

Post-treatment

- After discontinuation of guselkumab, patients should be followed up with medical history and physical examination
- For information regarding the ongoing need for contraception immediately following biologic treatment cessation, please see chapter “wish for child / pregnancy”

[1] due to personal-financial conflict of interest 3 abstentions

Recommendations for lab controls

Table 2: Recommended laboratory controls (Guselkumab)

	Period in weeks/months	
Parameter	**Pre-treatment**	**Thereafter, every 3-6 months**
Full Blood count	x	x
Liver enzymes	x	x
Serum creatinine	x	
Urine status	x	
Pregnancy test (urine or blood)	x	
CRP	x	
HBV/HCV	x	
HIV	x	
Interferon gamma release assay (TB exclusion)	x	

Not all tests may be necessary for all patients. Patient history, risk exposure and patient characteristics must be considered. Further specific testing may be required according to clinical signs, risk, and exposure.

The recommendations are based on clinical experience. No evidence is available.

Adverse drug reactions

Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects:

Overall, guselkumab was well tolerated in clinical trials in psoriasis. The most commonly reported adverse drug reactions were upper respiratory tract infections, and, less frequently, gastroenteritis, herpes, headache, diarrhoea, urticaria and arthralgias. Less than 1% of injections led to usually mild or moderate injection site reaction such as erythema.

Special consideration during treatment

Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects:

Surgery

The overall risk of infections in patients treated with anti-IL-23 antibodies (for example the rate of serious infections observed per 100 patient-years of exposure in clinical trials in psoriasis) appears to be comparable to that of other classes of targeted therapies in psoriasis; however, specific infections related to the mechanism of action, such as an increased Tb risk with TNFi and an increased risk of mucocutaneous candida infections with IL-17 inhibitors have not been reported for anti-IL-23 antibodies. There is only limited data available on the management of surgery in patients receiving anti-IL-23 treatment. The decision to interrupt guselkumab treatment prior to surgery must be based on individual factors, such as type and risk of surgical procedure, patient characteristics, individual infection risk etc. In case of continuing treatment, the procedure is best placed between two doses.

Important contraindications

Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects:

Absolute contraindications:

- Clinically relevant active infections such as active Tb

Relative contraindications:

- Acute, recurrent or chronic infections
- Pregnant or breastfeeding woman (due to lack of experience in humans)

Drug interactions

Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects:

Combination therapy with immunosuppressants, including biologics, or phototherapy have not been evaluated.

Overdose/ measures in case of overdose

In clinical trials single guselkumab doses of up to 10 mg/kg bodyweight have been administered intravenously and up to 300 mg subcutaneously with no observation of toxic effects. In the event of overdose, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions and appropriate symptomatic treatment be instituted immediately.