| JOB NO. | DESCRIPTION | DATE |
|---|---|---|
| HOSPUK1000:2 | Screening sheet v4 | 08/08/13 |

[Headline]
**INFLECTRA™ INFLIXIMAB):**
**Screening Sheet**

This checklist provides guidance for the screening and selection of patients. It highlights the contraindications and identified risks of treatment with INFLECTRA™.

| **1.0 Patient data** | | | | | | |
|---|---|---|---|---|---|---|
| 1.1 Patient name: | | | | | | |
| 1.2 Date of birth: | | | | | | |
| 1.3 Weight: | | | | | | |
| 1.4 Diagnosis: | Rheumatoid Arthritis | Ankylosing Spondylitis | Psoriatic Arthritis | Crohn's Disease | Ulcerative Colitis | Plaque Psoriasis |

| **2.0 Contraindications** | | |
|---|---|---|
| | YES | NO |
| 2.1 For the patient named above, is there any known hypersensitivity to: | | |
| i) The active ingredient infliximab or other murine proteins? | | |
| ii) Any one of the other ingredients? *(sucrose, polysorbate 80, sodium dihydrogen phosphate monohydrate, disodium phosphate dihydrate)* | | |
| 2.2 Does the patient currently have active tuberculosis (TB) or other severe infections such as sepsis, abscesses or opportunistic infections? | | |
| 2.3 Does the patient have moderate or severe cardiac insufficiency (NYHA III/IV)? | | |

**All questions in section 2 must be answered NO.**

| **3.0 Screening** | | |
|---|---|---|
| | YES | NO |
| 3.1 Is the patient known to have any of the following: | | |
| Risk of Hepatitis B (HBV) infection or known HBV infection? | | |
| Chronic or recurrent infection(s)? | | |
| Present or past history of malignant disease? | | |
| Ulcerative colitis (UC), with an increased risk for dysplasia or colon cancer (e.g. patients with long-term UC or primary sclerosing cholangitis), or with present or past history of dysplasia or colon cancer? | | |
| Mild cardiac insufficiency? | | |
| Severe asthma or a history of heavy smoking? | | |
| A demyelinating disease (e.g. multiple sclerosis or Guillain-Barré-syndrome)? | | |
| Liver dysfunction? | | |
| 3.2 Are any surgical procedures *(including dental)* scheduled for the patient? | | |
| 3.3 Has the patient visited regions where TB, fungal or other infections are endemic? | | |
| 3.4 Has the patient been vaccinated recently with live vaccines? *Please check vaccination status. If required, perform vaccinations with live vaccines **prior to** initiation of anti-TNF therapy. In children and adolescents* | | |

| | | |
|---|---|---|
| *with Crohn's disease, it is recommended to perform all vaccinations according to current recommendations prior to initiation of therapy.* | | |
| 3.5 Does the patient wish to have children?<br>*Women of childbearing potential must use adequate contraception to prevent pregnancy and continue its use for at least 6 months after the last INFLECTRA™ treatment.* | | |
| 3.6 Is the patient pregnant or breast-feeding?<br>*INFLECTRA™ is not recommended during pregnancy. Women must not breast-feed during and for at least 6 months after INFLECTRA™ treatment.* | | |
| 3.7 ***Rheumatology**:*<br>Is the patient receiving anakinra or abatacept? | | |
| 3.8 ***Plaque psoriasis**:*<br>Is there a history of extensive immunosuppressive therapy or prolonged PUVA (psoralen + UVA) treatment? | | |
| 3.9 ***Gastroenterology**:*<br>Is there combination therapy with azathioprine or 6-MP scheduled, or has the patient been treated with azathioprine or 6-MP, immediately prior to the intended INFLECTRA™ therapy? | | |

**Questions 3.1 to 3.9: If one or more of these questions are answered YES, consultation with the patient's treating physician is required.**

| | YES | NO |
|---|---|---|
| 3.10 Has a TB screening (medical history/chest X-ray) and tuberculin skin test or tuberculosis blood test been performed according to current guidance? | | |
| Test: | Date: | |
| | | |
| | YES | NO |
| 3.11 If latent tuberculosis has been diagnosed, has anti-tuberculosis therapy been initiated prior to anti-TNF therapy? | | |
| 3.12 Has the patient been comprehensively informed about the effect and administration of the drug; has the patient alert card been discussed with the patient, and will it be given to the patient at the time of the first dose of INFLECTRA™? | | |
| 3.13 Has the patient been informed about the importance of recording brand name and batch number for every infusion? | | |
| 3.14 Has the patient been informed about potential side effects and instructed to contact the physician in case there are any indications of severe infection or tuberculosis (such as persistent cough, wasting/weight loss, mild fever) or haematological reactions (e.g. persistent fever, bruising, bleeding, pallor)? | | |

**Questions 3.10 to 3.14 must be answered YES.**

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