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N&WICS - TA187 - Adalimumab - Severe active Crohn's disease (adults)

Before providing patient identifiable data on this form, please confirm that the patient (or in the case of a minor or vulnerable adult with the parent/legal guardian/carer) has given appropriate explicit consent for sensitive personal information on this form to be passed to the CCG and/or CSU for processing this funding request and validating subsequent invoices. Consent given: ☐

If there is more than one NICE-approved treatment available, a discussion between the responsible clinician and the patient has taken place about the advantages and disadvantages of the treatments available. This has taken into consideration therapeutic need and whether or not the patient is likely to adhere to treatment. The most appropriate, least expensive, will be chosen (taking into account administration costs, dosage and price per dose) unless an order of preference is stated in the TAs. ☐

Patient NHS No:	Trust:	Practice Name:
Patient Hospital No: <input type="text"/>	Consultant Making Request: <input type="text"/>	Practice Postcode:
Patient's Initials and DoB:		Practice Code:
Notification Email Address: <input type="text"/> (@NHS.net account ONLY)		Contact name & number: <input type="text"/>
Start date of requested treatment: <input type="text"/>	Provider: <input type="checkbox"/> Private <input type="checkbox"/> NHS Supplier: <input type="checkbox"/> Homecare <input type="checkbox"/> Hospital	Sub-Type: <input type="text"/> N/A <input type="button" value="v"/> (if applicable)

By completing this form, you confirm that you intend to use the requested medicinal product described below as agreed in the local commissioning statement. Any requests which fall outside of this use will require an individual funding request (IFR).

For support regarding IFRs, please contact: norfolkicd@nhs.net

For support regarding the criteria listed below, please contact: norfolknontariff@nhs.net

Please indicate whether patient meets the following NICE criteria:	Please tick
1. Adalimumab, within it's licensed indications, is recommended as treatment options for adults with severe active Crohn's disease (see Q4): <ul style="list-style-type: none"> • whose disease has not responded to conventional therapy (including immunosuppressive and/or corticosteroid treatments), or who are intolerant of or have contraindications to conventional therapy. • Adalimumab should be given as a planned course of treatment until treatment failure (including the need for surgery), or until 12 months after the start of treatment, whichever is shorter. • People should then have their disease reassessed (see 1.4) to determine whether ongoing treatment is still clinically appropriate. 	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Treatment as described in Q1 should normally be started with the less expensive drug (taking into account drug administration costs, required dose and product price per dose). This may need to be varied for individual patients because of differences in the method of administration and treatment schedules.	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Treatment with adalimumab should only be continued if there is clear evidence of ongoing active disease as determined by clinical symptoms, biological markers and investigation, including endoscopy if necessary. <ul style="list-style-type: none"> • Specialists should discuss the risks and benefits of continued treatment with patients and consider a trial withdrawal from treatment for all patients who are in stable clinical remission. • People who continue treatment with infliximab or adalimumab should have their disease reassessed at least every 12 months to determine whether ongoing treatment is still clinically appropriate. • People whose disease relapses after treatment is stopped should have the option to start treatment again. 	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Severe active Crohn's disease is defined as: <ul style="list-style-type: none"> • very poor general health and one or more symptoms such as weight loss, fever, severe abdominal pain and 	

<p>usually frequent (3–4 or more) diarrhoeal stools daily.</p> <ul style="list-style-type: none"> • people with severe active Crohn's disease may or may not develop new fistulae or have extra-intestinal manifestations of the disease. • this clinical definition normally, but not exclusively, corresponds to a Crohn's Disease Activity Index (CDAI) score of 300 or more, or a Harvey-Bradshaw score of 8 to 9 or above. 	<input type="checkbox"/> Yes <input type="checkbox"/> No		
<p>5. When using the CDAI and Harvey-Bradshaw Index, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect the scores and make any adjustments they consider appropriate.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No		
<p>6. Treatment with infliximab or adalimumab should only be started and reviewed by clinicians with experience of TNF inhibitors and of managing Crohn's disease.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No		
<p>7. As per NICE guidance, treatment should normally be started with the least expensive drug (considering the dose required, price per dose and any additional administration costs).</p> <p>Please confirm that the choice of drug is considered the most cost-effective treatment for this individual patient, noting that alternative treatment options recommended by NICE may be lower in cost, including the use of biosimilar medications if applicable.</p> <p>Where an alternative lower cost treatment is available and has not been tried by the patient, please confirm that the clinical rationale for prescribing has been included in the patients' medical record for the purpose of auditing.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No		
<p>8. The product is being used as described by local commissioning position.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No		
<table border="1"> <tr> <td data-bbox="66 835 659 1031"> <p>I confirm that the patient meets the criteria for treatment</p> <p>Name of person completing: <input type="text"/></p> <p>Designation of person completing: <input type="text"/></p> </td> <td data-bbox="659 835 1252 1031"> <p>Contact Details: <input type="text"/></p> <p>Date: <input type="text"/></p> </td> </tr> </table>		<p>I confirm that the patient meets the criteria for treatment</p> <p>Name of person completing: <input type="text"/></p> <p>Designation of person completing: <input type="text"/></p>	<p>Contact Details: <input type="text"/></p> <p>Date: <input type="text"/></p>
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<p>Trust Authorising Pharmacist</p> <p>Name: <input type="text"/></p> <p>Date: <input type="text"/></p>			