DISEASE MODIFYING THERAPY CARE
PATHWAY

Multiple Sclerosis Service
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CARE PATHWAY FOR DISEASE MODIFYING THERAPIES

<table>
<thead>
<tr>
<th>Patient is under the care of a Consultant Neurologist whether Newcastle, Middlesbrough or Sunderland</th>
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</thead>
</table>

Patient should given a 30 minute appointment with the Consultant Neurologist to:

- undertake a medical assessment on the patient to assess suitability / eligibility for treatment as per the specified Association of British Neurologist (ABN) criteria
- perform a baseline EDSS
- ensure the patient is committed to treatment
- answer any questions the patient/carer may have
- if patient is eligible details are forwarded to MS Specialist nurses

If the patient is under the care of either Newcastle, Middlesbrough or Sunderland, then details are forwarded to the MS Specialist nurse covering these areas, who will initiate therapy and follow up as below or liaise with the MS Service.

Patient is invited to attend a discussion about Disease Modifying Therapy:

- Written information on DMT’s are sent prior to appointment

Patients are informed about:

- how they meet the specified Association of British Neurologist (ABN) criteria for disease modifying therapies
- any contra-indications for use of therapy that may deem the patient unsuitable for treatment
- Patient expectations and outcomes.
- side effects appropriate to the therapy
- storage of the therapy
- information is provided on methods of delivery of the drugs – delivery company
- Base- line bloods to assess FBC, LFT, U&E’s, GGT, CRP, ESR, TFT, Coag Screen, Glucose and Electrophoresis
- follow-up process is discussed as below and patients commitment to the therapy ascertained
- the ABN stopping criteria is discussed
- patient/carer questions are answered
- a practical demonstration of all the therapy follows
- written information and video/DVD is provided on the therapy
- if patient undecided – they can take information and call when they have made a decision

Once patient has made a decision on the therapy the MS specialist nurses will:
Liaise with the MS Nurses and Neurologist for DMT prescription and initiation form
- Prescriptions to be signed by Consultant
- Prescription and initiation form is sent to the appropriate delivery company as the tertiary centres may use different delivery companies

Following delivery of the drug to the patient they need to contact the nurse to decide on a suitable starting date. This is usually within two weeks of delivery if there are no contraindications (relapse, infection etc) to commence treatment.

The patient is allocated a 60 minute appointment in a hospital setting to provide:
- instruction on administration of therapy
- supervision of first injection by the nurse
- review side-effects
- review correct storage of the drugs
- contact number of the nurse and delivery company
- the nurse must ensure the patient is competent and feels safe to administer the DMT
- the patient is contacted by phone by the nurse 24 hours post first injection to discuss side effects if required
- patients GP is informed that Disease Modifying Therapy has been initiated

Follow-up appointments in Year One

The patient is allocated appointments with the Specialist Nurse at one month, three months, six months, nine months and twelve months if blood tests are stable.

The following must be assessed:
- all relapses are documented, side effects and skin site reactions of treatment
- repeat and record all blood tests, FBC, LFT, U&E’s, GGT, CRP, ESR, Coag Screen, Glucose
- inform the patient of the results
- patients on interferon therapy will have bloods checked at all appointments, those on Copaxone will be checked at month one only (unless abnormal)
- MS nurse to complete DMT Review
- answer patient/carers questions
- inform the patients GP of progress
- if patient stops or a problem occurs then liaise with the Neurologist or MSSN's whose area the patient is from.

Neurologist Reviews

The patient is allocated an appointment to see the Consultant Neurologist as an outpatient:

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where they will be reviewed and this may include,
- documenting EDSS
- document other relevant information required by the DOH for those who are on the risk sharing scheme
- document progress - continuation/discontinuation of the therapy
- inform GP of the patients progress

Follow-up appointments after Year One

The patient is allocated a six monthly appointment for their Disease Modifying Therapy to be reviewed
- document as above all information required by the DOH for those who are on the risk sharing scheme
- MS nurses to complete DMT review for all patients on DMT. However, only those on Interferon therapy require blood to be taken for FBC, LFT, U&E’s, GGT, CRP, ESR, Coag Screen, Glucose
- repeat training record if required
- discuss continuation of therapy as appropriate
- inform GP of the patients progress
- if patient stops or a problem occurs then liaise with the Neurologist or MSSN’s whose area the patient is from.
APPENDIX ONE   MULTIPLE SCLEROSIS SERVICE DMT SHEET

Patient expectations
What does the patient understand that the treatment will achieve?

- Relapse rate reduction by one third
- Disease progression
- Reduced severity of relapses

Which product?
Has the patient received adequate information regarding product choice?

<table>
<thead>
<tr>
<th>Product</th>
<th>Frequency</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extaiva (interferon beta 1b)</td>
<td>every other day</td>
<td>under the skin</td>
</tr>
<tr>
<td>Avonex (interferon beta 1a)</td>
<td>once a week</td>
<td>into a muscle</td>
</tr>
<tr>
<td>Betaferon (interferon beta 1b)</td>
<td>every other day</td>
<td>under the skin</td>
</tr>
<tr>
<td>Rebif (interferon beta 1a)</td>
<td>three times a week</td>
<td>under the skin</td>
</tr>
<tr>
<td>Glatiramer Acetate (Copaxone)</td>
<td>every day</td>
<td>under the skin</td>
</tr>
</tbody>
</table>

Does the patient understand?

- How the treatment will be dispensed or collected
- Storage requirements eg need for refrigeration
- Method of administration ie sub-cutaneous or intra muscular
- Frequency of administration

Pre-treatment monitoring
Prior to treatment several blood tests need to be carried out. The results of these tests need to be known to the Neurologist before the treatment can be started.

<table>
<thead>
<tr>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coag Screen, Glucose and Electrophoresis</td>
</tr>
<tr>
<td>FBC, U&amp;E’s, LFT, GGT, TFT, CRP, ESR</td>
</tr>
</tbody>
</table>

Potential side-effects discussed
These are the most common side-effects that might be expected. These should be discussed with the MS Specialist Nurse.

- Flu like symptoms
- Injection site reactions
- Altered bloods
- Depression
- IPIR (Copaxone only)
- Other

Side-effect management discussed

- Prophylactic paracetamol or ibuprofen
- Timing of injection ie at night
- Rotation of injection sites
- Reporting of side effects
- Monitoring required by MS nurses and Consultant
Pregnancy and contraception

<table>
<thead>
<tr>
<th>Importance of effective contraception</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Stopping of treatment prior to pregnancy</td>
<td></td>
</tr>
<tr>
<td>Options for treatment following child birth</td>
<td></td>
</tr>
</tbody>
</table>

Monitoring requirements

Whilst taking treatment commitment to regular follow up is essential

<table>
<thead>
<tr>
<th>Commitment to clinic appointments</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood monitoring</td>
<td></td>
</tr>
<tr>
<td>Reporting of side-effects</td>
<td></td>
</tr>
<tr>
<td>Relapse management / reporting</td>
<td></td>
</tr>
<tr>
<td>MS Nurse and Consultant follow up</td>
<td></td>
</tr>
</tbody>
</table>

Reason for stopping treatment

As well as there being strict starting criteria for disease modifying treatments, there are also stringent stopping criteria which must be considered before starting treatment

<table>
<thead>
<tr>
<th>Unmanageable side-effects eg flu like symptoms, site reactions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Bloods</td>
<td></td>
</tr>
<tr>
<td>Lack of efficacy</td>
<td></td>
</tr>
<tr>
<td>Relapses</td>
<td></td>
</tr>
<tr>
<td>Progression of disability</td>
<td></td>
</tr>
<tr>
<td>Non attendance at monitoring appointments</td>
<td></td>
</tr>
<tr>
<td>Switching product</td>
<td></td>
</tr>
</tbody>
</table>

These issues have been fully discussed and the patient has been given adequate time for questions and discussion

..................................................................................................................
..................................................................................................................
..................................................................................................................

NAME OF PATIENT                                                   SIGNATURE OF PATIENT      DATE
..................................................................................................................
..................................................................................................................
..................................................................................................................

NAME OF MS NURSE                                                  SIGNATURE OF MS NURSE      DATE
..................................................................................................................
..................................................................................................................
..................................................................................................................

THERAPY NOT TO BE COMMENCED UNTIL BLOOD RESULTS HAVE BEEN CHECKED

<table>
<thead>
<tr>
<th>BLOOD RESULTS CHECKED</th>
<th>BY WHOM</th>
<th>DATE</th>
</tr>
</thead>
</table>

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APPENDIX 2

WHO TO CONTACT

For some, starting disease modifying therapies can be quite a daunting time. You are given a great deal of information regarding your therapy. Numerous people are also involved in the process of you receiving your therapy. It can become a little confusing at times, as to who to contact with a problem or question. The following aims to give you some guidance as to who to contact.

DELIVERY COMPANY

- To alter or query a delivery date
- If you have run out of medication
- If something has happened to your medication ie your fridge has broken
- If you did not receive your delivery as scheduled
- If you need a double delivery because you are going on holiday
- If you require a new sharps box
- If you require a full sharps box to be collected
- If you need a replacement cool bag / ice blocks
- If you need a new diary
- If you are stopping treatment and need your therapy, sharps box etc to be collected

MS SERVICE

- If you have any questions regarding your
  - MS
  - Your therapy
  - Other medications
- If you have any questions / concerns regarding
  - If you want to stop your therapy
  - Skin site reactions
  - Side effects
  - Missed injections
  - If you think you may have injected twice
  - If you require retraining for manual injections or the autoject
  - If you are finding it difficult to inject
  - Travelling with your therapy

DRUG THERAPY HELPLINES

- You can contact the helpline regarding any of the issues listed in the MS nurse list, however, still leave a message for your MS nurse
- However, we would ask you to try and contact your MS nurse first unless it is out of working hours
APPENDIX 3

DISEASE MODIFYING DISCUSSION

WHAT HAPPENS NEXT?

- You will be contacted by a dispensing company prior to you receiving the delivery of your drugs.
- You will then have your drugs delivered to your place of choice.
- Contact us on 01388 452289/452264 to inform us that you have received your drugs.
- **DO NOT START YOUR TREATMENT UNTIL YOU HAVE BEEN TRAINED BY A NURSE**
- Prior to your training session please watch and read the training material provided by the company of the drug you have chosen.
- We will send you an appointment to attend a training session.
- When you attend the training session please bring with you the following:-
  - A relative or friend
  - Two of everything in your drug pack including the drug itself
  - Some paracetamol
  - **You will perform your first injection at this session**
  - **Please be aware that you may need to return for a second training day**

- We will follow you up the first week by phone calls.
- You will be provided with helpline telephone numbers by your dispensing company.
- You will receive your review appointments via the post following your training.
**APPENDIX 4: PATIENT DMT TRAINING RECORD**

Name of nurse.....................................................  Date of training.....................

<table>
<thead>
<tr>
<th>CHECKLIST FOR TRAINING OF</th>
<th>COMPLETED</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Expectations of therapy i.e. reduction of relapses and severity</td>
<td></td>
</tr>
</tbody>
</table>
| 2. Storage of therapy – temp  
  - fridge  
  - child proof containers  
  - cupboards away from children |           |
| 3. Disposal of sharps - what goes into sharps box  
  - who to contact for disposal  
  - safe storage of sharps box |           |
| 4. When to take out of the fridge prior to injection – 30 to 60 mins |           |
| 5. Possible side effects of the drug ie flu like symptoms (interferons) or chest tightness (copaxone) have been explained |           |
| 6. What action/intervention to use for side effects ie flu like symptoms (ibuprofen or paracetamol) or chest tightness (stay calm) |           |
| 7. Injection sites appropriate for the chosen therapy have been demonstrated |           |
| 8. The importance rotating the injection sites has been explained |           |
| 9. Possible skin site reactions and the appropriate action to take have been explained - ensure skin clean to the eye  
  - avoid the use of lotions/fake tan/sun beds  
  - only use witch hazel, arnica cream or aloe vera on injection sites other products may cause irritation  
  - report any injection site problems to your MS nurse  
  - avoid rubbing the area post injection  
  - use a clean tissue / cotton wall ball to dab the area |           |
| 10. Both methods of injection demonstrated – manual and autoject (settings) |           |

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11. Titration for Rebif has been demonstrated

12. Who to contact for delivery problems

13. Who to contact for any problems with injections, skin site reactions, side effects or problems with MS
   - first port of call is your MS nurse
   - or contact the drug helpline

14. Information regarding travelling / holidays given
   - holiday letter
   - checking with the airline / travel company
   - storage facilities available ie fridge

Signature of nurse..............................................................................................................

Date........................................

Signature of patient...............................................................................................................

Date.........................................