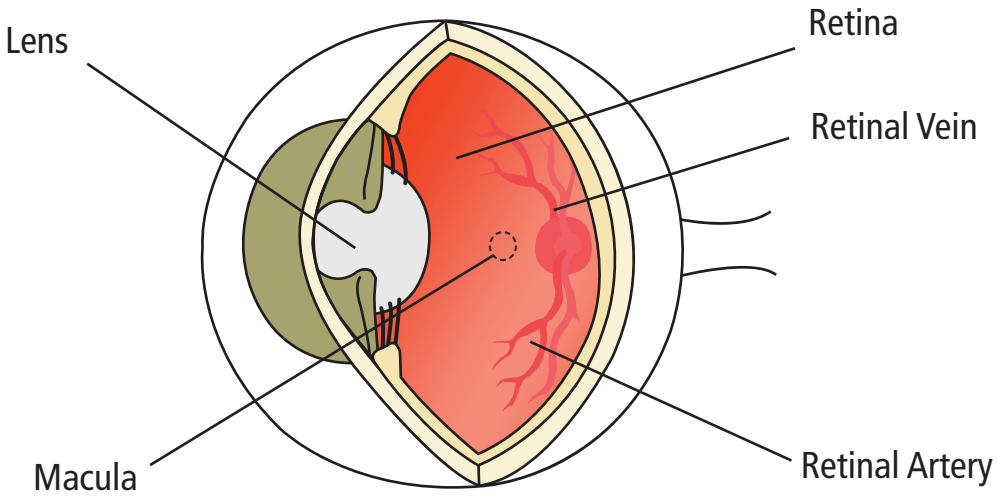
NHS
Royal Cornwall Hospitals
NHS Trust

Diabetic macular oedema (DMO)

affix patient label

What is the macula?

The tissue at the back of the eye is called the retina and can be thought of as being like the film in a camera. The central part of the retina is called the macula. The macula provides detailed sharp central vision and the ability to appreciate colour.



What is diabetic macular oedema (DMO)?

Diabetes damages capillaries (tiny blood vessels) in your retina. This damage can either lead to leakage of fluid from your bloodstream into your retinal nerve layer or blockage of the blood supply, starving your retina of oxygen. The leakage causes oedema (waterlogging). When this affects the macula – the centre of your retina – it is known as diabetic macular oedema (DMO).

Who is at risk of DMO?

There is no known cause but cells in the macula break down due to the aging process. Important risk factors are a family history of ARMD and smoking tobacco. Less commonly, macular degeneration can occur in severely shortsighted people or certain genetic conditions.

What are the symptoms?

Anyone who suffers from Type 1 or Type 2 diabetes can develop DMO.
The risk is increased if you:

- have had diabetes for a long time – about 1 in 3 people living with diabetes for 20 years or more will develop diabetic macular oedema
- have poorly controlled blood sugars (High HbA1C)
- high blood pressure

- have high cholesterol levels
- are a smoker
- are pregnant.

What are the symptoms?

Waterlogging (oedema) of the macula does not allow the image to form properly on your retina. This causes blurred vision. A healthy macula is essential for good vision. Reading, writing, or any other close work such as knitting are affected the most.

How is it diagnosed?

DMO may be detected during an annual eye screening visit or during an outpatient clinic appointment. Sometimes scans or photographs taken of your retina may show early signs ofDMO but at this stage there may not be any symptoms of blurred vision. If significant DMO is found, you will be referred to a specialist clinic.

What happens at the specialist clinic?

You will have several tests to determine the extent of your DMO:

Visual acuity test – to see how well you can see

Optical Coherence Tomography (OCT) scan – an optical scan which uses a light beam to build up a detailed picture of the macula

Examination of the retina – drops are instilled to dilate your pupils, so the specialist can look at the back of your eye to assess the macula and the rest of the retina.

Are any other tests required?

You may need an additional test called Fundus Fluorescein Angiography. In this test a fluorescent dye is injected into your arm and photographs are taken of the dye as it passes through the blood vessels at the back of your eye. This test is done on a different day rather than on the day of your outpatient appointment.

How is DMO treated?

The treatment for DMO depends on how severe the oedema is. This is determined with an OCT retinal scan to measure the thickness of the retina.

- **Observation** – in some patients, DMO can resolve spontaneously. In these cases, this can be just monitored regularly in the clinic.
- **Laser treatment to the macula** – this involves applying laser burns in the macular region. Several applications are given in a session and more than one session may be needed. Laser treatment is not beneficial in all cases.

- **Injection of anti-vascular endothelial growth factor (anti-VEGF) drugs in the eye** – there are two anti-VEGF drugs (Lucentis and Eylea) which work on leaky blood vessels to help reduce fluid in the macula. Injections are given in an outpatient setting under local anaesthesia. One injection is given every month to begin with. After that further injections are given on a regular basis.
- **Injection of steroid implant in the eye** – a very small dissolvable steroid implant (called Ozurdex) is injected in the eye under local anaesthesia. The effect of treatment lasts 3-4 months and it can be repeated thereafter. Another type of steroid implant (called Iluvien) lasts for up to three years following injection.

Which treatment is most effective?

Research trials have shown the most effective treatment for improving sight is anti-VEGF injections, followed by the steroid implant and then laser treatment. However NICE recommends treatment with anti-VEGF or steroid only when the retinal thickness is more than 400 microns on the OCT retinal scan. A combination of treatments may be more effective and your doctor will discuss this with you if appropriate.

How is the injection given?

It is an outpatient procedure and takes only a few minutes:

1. The nurse will instill antiseptic and local anaesthetic drops into your eye and then the eye will be cleaned with an antiseptic solution.
2. The injection is given into the eye. It is not a painful procedure but most people describe it as a brief 'sharp scratch'.
3. You will be asked to wait for a short time before going home to ensure there are no problems.

What are the side effects?

You may experience temporary blurring of vision and minor discomfort for a day. Some patients experience severe pain for a day or two. We advise you to use plenty of lubricating eye drops during this time. You may see a few 'floaters' or 'bubbles' for a few days.

Are there any risks or complications?

As with all procedures, there are some possible risks, but the benefits usually outweigh the risks. An Anti-VEGF injection carries a small risk (0.3%) of sight-threatening infection in the eye (endophthalmitis). There is a small risk of glaucoma (increased pressure in the eye) and cataract (cloudy lens). With frequent injections there is a small risk (1-2%) of cardiovascular events such as heart attack and stroke.

With Ozurdex and Iluvien treatment the main risks are glaucoma (increased pressure in the eye) and cataract (cloudy lens) in approximately 25% cases. The injection carries a small risk (0.3%) of sight-threatening infection in the eye (endophthalmitis).

In all cases, there is a very small risk of accidental injury to lens, retina or other eye structures. The risk of total sight loss due to any complication is less than 1 in 1000.

When to contact the hospital?

If you experience sudden loss of vision after injection especially associated with severe pain, you should contact emergency number 01872 252324.

How long will I need treatment?

If the treatment is successful initially, it will continue indefinitely as long as the benefits outweigh the risks. However, if treatment fails to relieve macular oedema in the first instance further treatment should be stopped. If your DMO completely resolves, the treatment can be discontinued temporarily.

Does the treatment work for everyone?

Sometimes despite successfully treating the swelling at the back of your eye, the vision fails to improve. This is a result of lack of oxygen caused by blocked blood vessels. Sometimes the treatment does not improve the macular swelling and sometimes the vision gets worse because of a worsening of the complications from the treatment as described above.

Any questions?

This leaflet provides just an overview of retinal vein occlusion. If you have any questions please don't hesitate to speak to us during your clinic visit. Further information can also be obtained by contacting:

Royal National Institute for Blind (RNIB) on 0303 123 9999 or

Macular Disease Society (MDS) on 0300 3030 111

If you would like this leaflet in large print, Braille, audio version or in another language, please contact the General Office on 01872 252690

Patient copy

CONSENT FORM 1
PROCEDURE SPECIFIC PATIENT AGREEMENT

NHS
Royal Cornwall Hospitals
NHS Trust

NHS number: .....
Name of patient: .....
Address: .....
Date of birth: .....
CR number: .....

AFFIX PATIENT LABEL

Diabetic macular oedema

Intravitreal injection of therapeutic drug

STATEMENT OF HEALTH PROFESSIONAL (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

Procedure: Intravitreal injection (injection in to the jelly of the eye)

Drug to be injected: Lucentis ☐ Eylea ☐
Ozurdex ☐ Other (please specify): _____
Eye: Right eye ☐ Left eye ☐

I have explained the procedure to the patient. In particular, I have explained the intended benefits:

- *Prevent rapid vision loss*

Significant, unavoidable or frequently occurring risks

- *Temporary blurring of vision, minor discomfort, seeing a few 'floaters' or 'bubbles', cataract formation, glaucoma (build up of pressure in the eye).*

Uncommon but more serious risks:

- *Severe pain or discomfort lasting 2-3 days*
- *Accidental injury to structures (lens, retina) inside the eye.*

Rare but serious risks:

- *Infection in the eye causing total sight loss*
- *Cardiovascular event such as stroke and heart attack.*

Any extra procedures which may become necessary during the procedure:

- *Other procedure (please specify):*

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

I have given and discussed the Trust's approved patient information leaflet for this procedure: Diabetic Macular Oedema CHA4224 which forms part of this document.

I am satisfied that this patient has the capacity to consent to the procedure.

This procedure will involve: ☐ General and/or regional anaesthesia ☐ Local anaesthesia ☐ Sedation

Health Professional signature: ..... Date: .....

Name (PRINT): ..... Job title: .....

STATEMENT OF INTERPRETER (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe he/she can understand.

Interpreter signature: ..... Name (PRINT): ..... Date: .....

affix patient label

Diabetic macular oedema consent form

STATEMENT OF PATIENT

Please read this form carefully. If your treatment has been planned in advance, you should already have a copy of the patient information leaflet which describes the benefits and risks of the proposed treatment. If not, you will be given a copy now. If you have any further questions, do ask - we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia).

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I understand that tissue samples will only be taken in relation to the procedure explained to me. No samples will be taken for quality control, clinical education or research purposes.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures **which I do not wish to be carried out** without further discussion.

I have received a copy of the Consent Form and Patient Information leaflet: Diabetic Macular Oedema CHA4224 which forms part of this document.

Patient signature: ..... Name (PRINT): ..... Date: .....

A **witness** should sign below if this patient is unable to sign but has indicated his or her consent.
Young people / children may also like a parent to sign here (see guidance notes).

Witness signature: ..... Name (PRINT): ..... Date: .....

CONFIRMATION OF CONSENT (to be completed by health professional when the patient is admitted for the procedure, if the patient has signed the form in advance).

On behalf of the team treating the patient, I have confirmed with the patient that they have no further questions and wish the procedure to go ahead.

Health Professional signature: ..... Date: .....

Name (PRINT): ..... Job title: .....

Important notes (tick if applicable):

☐ See advance decision to refuse treatment ☐ Patient has withdrawn consent (ask patient to sign/date here)

Patient signature: ..... Name (PRINT): ..... Date: .....

File copy

CONSENT FORM 1
PROCEDURE SPECIFIC PATIENT AGREEMENT

NHS
Royal Cornwall Hospitals
NHS Trust

NHS number: .....
Name of patient: .....
Address: .....
Date of birth: .....
CR number: .....

AFFIX PATIENT LABEL

Diabetic macular oedema

Intravitreal injection of therapeutic drug

STATEMENT OF HEALTH PROFESSIONAL (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

Procedure: Intravitreal injection (injection in to the jelly of the eye)

Drug to be injected: Lucentis ☐ Eylea ☐
Ozurdex ☐ Other (please specify): _____

Eye: Right eye ☐ Left eye ☐

I have explained the procedure to the patient. In particular, I have explained the intended benefits:

- *Prevent rapid vision loss*

Significant, unavoidable or frequently occurring risks

- *Temporary blurring of vision, minor discomfort, seeing a few 'floaters' or 'bubbles', cataract formation, glaucoma (build up of pressure in the eye).*

Uncommon but more serious risks:

- *Severe pain or discomfort lasting 2-3 days*
- *Accidental injury to structures (lens, retina) inside the eye.*

Rare but serious risks:

- *Infection in the eye causing total sight loss*
- *Cardiovascular event such as stroke and heart attack.*

Any extra procedures which may become necessary during the procedure:

- *Other procedure (please specify):*

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

I have given and discussed the Trust's approved patient information leaflet for this procedure: Diabetic Macular Oedema CHA4224 which forms part of this document.

I am satisfied that this patient has the capacity to consent to the procedure.

This procedure will involve: ☐ General and/or regional anaesthesia ☐ Local anaesthesia ☐ Sedation

Health Professional signature: ..... Date: .....

Name (PRINT): ..... Job title: .....

STATEMENT OF INTERPRETER (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe he/she can understand.

Interpreter signature: ..... Name (PRINT): ..... Date: .....

File copy

affix patient label

Diabetic macular oedema consent form

STATEMENT OF PATIENT

Please read this form carefully. If your treatment has been planned in advance, you should already have a copy of the patient information leaflet which describes the benefits and risks of the proposed treatment. If not, you will be given a copy now. If you have any further questions, do ask - we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia).

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I understand that tissue samples will only be taken in relation to the procedure explained to me. No samples will be taken for quality control, clinical education or research purposes.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures **which I do not wish to be carried out** without further discussion.

.....

I have received a copy of the Consent Form and Patient Information leaflet: Diabetic Macular Oedema CHA4224 which forms part of this document.

Patient signature: ..... Name (PRINT): ..... Date: .....

A **witness** should sign below if this patient is unable to sign but has indicated his or her consent.
Young people / children may also like a parent to sign here (see guidance notes).

Witness signature: ..... Name (PRINT): ..... Date: .....

CONFIRMATION OF CONSENT (to be completed by health professional when the patient is admitted for the procedure, if the patient has signed the form in advance).

On behalf of the team treating the patient, I have confirmed with the patient that they have no further questions and wish the procedure to go ahead.

Health Professional signature: ..... Date: .....

Name (PRINT): ..... Job title: .....

Important notes (tick if applicable):

☐ See advance decision to refuse treatment ☐ Patient has withdrawn consent (ask patient to sign/date here)

Patient signature: ..... Name (PRINT): ..... Date: .....