**Vaccine Damage Payment Scheme**

**Principles of Medical Assessment**

**1. Introduction**

This document outlines the quality standards expected within the Vaccine Damage Payment Scheme (VDPS) medical assessment reports. It also incorporates previous learning that may be useful to consider in the preparation of reports.

The Vaccine Damage Payments Act (VPDA) 1979 states where ‘on the balance of probability’ it is determined that a person is, or was immediately before their death, severely disabled due to a vaccination against any of the specified diseases, a lump sum payment will be made in accordance with the Act.

Disablement is assessed in accordance with the Social Security Contributions and Benefits Act 1992.

When originally passed, the Vaccine Damage Payments Act defined severe disablement as in excess of 80%. From 16/06/2002, this was changed to being defined as disablement of 60% or more.

The VDPA 1979 provides for payments to be made for disablement as a result of the vaccine itself (actual substance). Claims arising from administrative errors are not covered under the VDPS Act and therefore are not eligible for consideration under the VDPS.

**2. Core principles**

When conducting a VDPS medical assessment and producing an outcome report there are core principles that should be demonstrated:

* Impartiality, fairness and objectivity
* Justification for the outcome must be robust and stand up to scrutiny
* Up to date evidence/information must be considered and comprehensively analysed
* Consideration of hierarchy of evidence/information must be applied consistently
* Approach must be professional, in line with GMC expectations.

**3. Medical Assessment**

All claims are assessed by the independent medical assessment company, (the Provider) with a consistent approach. Each case is considered on its own merits, by an experienced independent medical assessor, all of whom are General Medical Council registered doctors with a licence to practise. Medical assessors will consider clinical research, epidemiological evidence, and the current consensus of expert medical opinion~~’~~ together with a claimant’s application and their medical records from their healthcare providers to make a clinical assessment on whether it is more probable than not that the vaccine has caused disablement, and if so, whether that disablement is severe.

Claims for Vaccine Damage payment will bereferred to medical assessors for advice on:

1. Causation (Whether any disablement has been caused by the vaccine, on balance of probability)
2. Disablement (Where the vaccine has caused disablement, the level of disablement caused by the vaccine and whether the impact of the disablement may change over time).

**General principles**

* The independent medical assessor will review the eligibility of the claim according to the current list of eligible vaccines for relevant age groups,[Vaccine Damage Payment: Eligibility - GOV.UK (www.gov.uk).](https://www.gov.uk/vaccine-damage-payment/eligibility)  (Exceptions to the list may be applicable where the claimed vaccine has been given as part of a combined vaccine where at least one component of the vaccine is covered by the scheme in the relevant age group.)
* The independent medical assessor will review the information presented and determine if there is sufficient information available to complete the assessment.
* Where a claim is made exclusively for short term, well recognised side effects (SE) as listed in the commonly referenced credible sources (such as the Green Book, Summary of Product Characteristics, Product information Leaflets) and no long-term disablement from the vaccine is evident from the claim or the medical evidence, then causation is rejected and may be justified using a suitable phrase.
* There may be some cases where it appears all information required to carry out an assessment is not available, such as hospital or GP records have not been provided. Where this is the case, the medical assessor must advise NHSBSA that additional evidence is required. The Provider must advise NHSBSA what evidence is explicitly missing (e.g. type, time period etc). NHSBSA will then request this information.
* There may be occasions where some information may be missing (e.g. Part of historical medical records) but a complete and thorough assessment can still be carried out. The medical assessor will record in the report what information has been used to carry out the assessment and what the assessment is based on. There must be an acknowledgment from the MA that despite the stated documentation being missing, a complete and thorough assessment has been completed.
* Clinical diagnosis should normally be accepted without a need to review. Where clinical diagnosis does not exist, the described symptoms will be considered. Clinical diagnosis is not required to undertake a VDPS medical assessment.

**3.1 Assessing Causation**

Determining causation is fundamental to the medical assessment. Causation is determined “**on the balance of probabilities**” and this phrase must be used within the report. Determination of causation on the balance of probabilities requires in depth weighing of evidence including temporality, biological plausibility, epidemiology and the individual facts of the case.

The report must be appropriately detailed to robustly justify why causation should be accepted or rejected and sources of evidence must be referenced including where relevant, confirmation of the version of evidence that has been used (e.g. the Green Book, Summary of Product Characteristics). This includes listing relevant document numbers of medical evidence from the file and justifying opinions and conclusions with appropriate references.

There must be a clear explanation of scientific and medical issues such that the report can be clearly understood by a non-medical person. Any underlying scientific or medical reasoning and all medical terminology must be clearly explained.

**Considerations**

3.1.1 Temporal link

The vaccine must predate the onset of the claimed symptoms for a temporal link to be possible and there must be a link in time between the two which is biologically reasonable or within limits defined in published research. The existence of a temporal link does not necessarily imply causation, but it is a prerequisite.

3.1.2 Biological plausibility

For causation to be possible, there must be a scientifically plausible mechanism that would be accepted by the body of medical opinion, to explain how the vaccine has led to the claimed diagnosis/damage. Research in this field is constantly evolving. Sources of research quoted must be independent, current, credible, robust sources of medical evidence with references stated.

 A biologically plausible mechanism may support causation but is not sufficient on its own to establish causation.

3.1.3 Sources of information available to use to establish or refute causation

All sources of information should be carefully evaluated when deciding “on the balance of probability” whether causation is accepted. Discrepancies must be addressed, and an explanation given for why one piece of evidence has been favoured over another.

3.1.4 Hierarchy of evidence

Evidence can be ranked according to its relative strength. The stronger the evidence, the more weight it carries, and population level data is considered to be the strongest.

Whilst all available evidence needs to be considered the assessor must factor into their advice the weight of any particular evidence especially in cases where evidence may be conflicting.

In such cases where evidence is conflicting the assessor will need to explain why they find one evidence source more compelling than another.

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3.1.4.1 Population level data

* Independent medical assessors use credible resources to support their assessment including, but not limited to:
* Medicines and Healthcare products Regulatory Agency (MHRA) regulatory position summaries and data including Yellow Card information on suspected safety concerns involving a healthcare product. [Yellow Card | Making medicines and medical devices safer (mhra.gov.uk)](https://gbr01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fyellowcard.mhra.gov.uk%2F&data=05%7C01%7Cchris.gooday%40nhs.net%7C608efc1d0f9a4bafde1308dadd0006e9%7C37c354b285b047f5b22207b48d774ee3%7C0%7C0%7C638065289418303539%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=3asFcGOsTTZrrOR1JEtrMFs2hj3Xr3ppYb3cDL0YpLk%3D&reserved=0) [Coronavirus vaccine - summary of Yellow Card reporting - GOV.UK (www.gov.uk)](https://gbr01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fpublications%2Fcoronavirus-covid-19-vaccine-adverse-reactions%2Fcoronavirus-vaccine-summary-of-yellow-card-reporting&data=05%7C01%7Cchris.gooday%40nhs.net%7C608efc1d0f9a4bafde1308dadd0006e9%7C37c354b285b047f5b22207b48d774ee3%7C0%7C0%7C638065289418303539%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=e6SIPPjX61JRa1GxzCOVaMpWaOmLg%2BvUsptGskitJL8%3D&reserved=0)
* Vaccine product information and updates  (e.g. Summary of Product Characteristics and Patient Information Leaflets)
* The Green Book – A reference material produced by UK Health Security Agency and used by healthcare professionals in the UK. The Green Book brings together all documents relating to immunisation against infectious diseases. [Immunisation against infectious disease: the green book front cover and contents page - GOV.UK (www.gov.uk)](https://gbr01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fpublications%2Fimmunisation-against-infectious-disease-the-green-book-front-cover-and-contents-page&data=05%7C01%7Cchris.gooday%40nhs.net%7C608efc1d0f9a4bafde1308dadd0006e9%7C37c354b285b047f5b22207b48d774ee3%7C0%7C0%7C638065289418303539%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=USmUlx9ePz1ZrtZqUstSnXunapDSMywvg4uEJeszThs%3D&reserved=0) Information is sought from the latest version.
* WHO publications

3.1.4.2 Absence of population level evidence

Where population level data is not available, advice will be based on the available evidence, giving consideration to the hierarchy of evidence and the individual facts of the case.

Where there has been extensive epidemiological monitoring which has not established a link between a given vaccine and a stated condition, this may suggest a lack of support to establishing a causal link.

3.1.4.3 Peer reviewed academic based research

Wherever possible, high quality peer reviewed research will be used to establish causation advice. This ensures that the validity, quality and integrity of the research has been scrutinised by experts in the same field and invalid or poor quality articles are filtered out. Sources may include:

* Cochrane library
* British medical journal publications
* PubMed

3.1.4.4 Non peer reviewed research (e.g. Case studies)

This information is considered less reliable than peer reviewed information but may be used as an adjunct for advice.

Examples include:

* Non peer reviewed scientific Journal article
* Case studies

3.1.4.5 Individual case level data

The facts established from the file of medical evidence may include:

* The treating clinician’s opinion on causation may be recorded in the medical notes. The clinician’s opinion will be considered and weighed against other evidence in the report.
* Yellow card information. If a yellow card was completed by medical personnel, this will be recorded. Completion of a yellow card only suggests a suspected adverse reaction
* Postmortem documentation
* Coroner’s report
* Death certificate

In cases where the decision on causation appears not to align with the population level data (e.g. regulatory position, MHRA summaries) the report will include robustly justified rationale based on the particular circumstances of the individual case and will stand up to scrutiny.

3.2 Further Expertise required

Due to the nature of the case and the availability of scientific evidence the medical assessor may believe further expert opinion is required in order to provide advice on causation. Such a case must be escalated and designated as a ‘Complex’ case requiring expert opinion. Next steps and timeline will be agreed with the NHSBSA. Once the expert advice has been obtained it will be recorded in the medical assessment report that additional advice has been sought from a named expert. The level of involvement of the expert will be stated in the report and advice given by the expert added to the file.

3.3 Causation statement

Causation is accepted when following a review and consideration of all the available evidence, it is concluded that on the balance of probabilities, it is more likely than not that the claimed condition(s) resulted from the vaccine.

For causation to be accepted, the medical assessor will have given consideration to all the available evidence and facts of the case. Topics including confirmation of administration of the claimed vaccine, temporality between vaccine and claimed condition(s), biological plausibility, weight of scientific/epidemiological research and the lack of any more plausible explanation, will all have been considered and given appropriate ‘weighting’ as part of the assessment process.

**4. Assessing Disablement**

According to the Vaccine Damage Payment Act 1979 (VDPA) subject to the fulfilment of conditions of entitlement being met, a payment shall be made if a person is, or was immediately before his death, severely disabled as a result of vaccination against any of the diseases to which this Act applies.

A person shall be deemed severely disabled if the disablement is assessed as severe (60% or more). Assessment of the level of disablement will be carried out in accordance with [Section 103](https://www.legislation.gov.uk/ukpga/1992/4/section/103) of the Social Security Contributions and Benefits Act 1992 and Schedule 2 of [The Social Security (General Benefit) Regulations 1982 (legislation.gov.uk)](https://www.legislation.gov.uk/uksi/1982/1408/schedule/2)

The VDPA also states that if a person is assessed to be severely disabled, the question whether his severe disablement results from vaccination against any of the diseases to which the Act applies shall be determined for the purposes of the Act on the balance of probability.

Where the vaccine has caused disablement, the level of disablement caused by the vaccination and whether the impact of the disablement may change (ie. Increase or decrease) over time will be considered and clearly stated in the report.

Key Principles of Disablement Assessment cover:

* Loss of faculty and disablement
* Multiple contributions to level of disablement
* Offset of existing disablement
* Comparators
* Aids/prostheses
* Future deterioration
* Future improvement

4.1 Loss of faculty and disablement

A diagram of injury and relevant disability

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In Vaccine Damage Payment claims, the claim is made that a vaccination has caused an injury which leads to a loss of faculty. This gives rise to a disability which results in an overall level of disablement.

4.1.1 Loss of faculty (LoF):

This is defined as the restriction in function resulting from the injury and from which disablement results.

This may be a total or partial loss of power or function of an organ/part of body. (For example, loss of muscle and skin right lower limb; loss of functioning brain tissue; loss of skin integrity, disfigurement; reduced confidence, low mood). It is not a disability in itself, but it is a cause (actual or potential) of disability/ies. It can be judged by comparing the individual’s condition before the vaccine to their condition after it.

Aids are not considered when determining the loss of faculty.

Following Upper Tier Tribunal Judgements, it is required that the loss of faculty is specified when determining the assessment of disablement.

4.1.2 Disability and Disablement:

Disability is the inability (total or partial) to perform a normal bodily process to the expected degree of a person of the same age and sex, whose physical and mental condition is normal. This reference must be made in the report. Aids are considered.

Disablementis the overall effect of the relevant disabilities on the capacity to perform the normal activities of daily living, or loss of health, strength, power and mental activity to enjoy normal life.

For vaccine damage payment purposes, only disablement caused by vaccination will be taken into account and disablement of 60% or more is said to be severe.

4.2 Multiple contributions to level of disablement

Where causation is accepted, it is essential to consider all conditions/symptoms that are caused or worsened by the effects of the vaccine.

* What is the accepted loss of faculty/faculties? (Any differences between this and that which is stated in the claim form must be explained).
* Is the vaccine the whole cause for this?
* Is there any other cause of the loss of faculty? (There may be multiple causes of loss of faculty/overall level of disablement in an individual. In a disabled person, it is possible that only part of the disablement may be relevant to the vaccine. Hence any significant Past Medical History which impacts the relevant loss of faculty and causes an overlapping disability must be listed and considered . Any appropriate deductions to the overall disablement must be made and this should be used to clearly justify the disablement advice).

4.2.1 Loss of faculty

|  |  |
| --- | --- |
| **Fully Relevant to the vaccine** | Vaccine is the only cause |
| **Partially Relevant to the vaccine** | Vaccine is part of the cause |
| **Unconnected to the vaccine** | Has no causal link to the vaccine |

4.2.2 Advice given in VDPS cases must relate to the total relevant disablement resulting from the stated loss/es of faculty/ies The process by which this has been calculated must be evident in the report.

4.2.3 Partially relevant conditions

All partially relevant conditions must be considered and the fully relevant parts of these (i.e. those which have been caused by the vaccine) are added together to give the total relevant disablement.

4.2.4 Consequential injuries/conditions

Where causation has been accepted for a given condition, the situation may arise where a subsequent condition/injury occurs as a result of the accepted condition.  Any consequential LoF from this secondary condition is therefore considered relevant and requires consideration.

4.2.5 Interaction addition

Where a condition arises post vaccination and is not causally linked to the vaccine, but has a loss of faculty which overlaps with the stated loss of faculty from the vaccine, the relevant disablement caused by the vaccine is made slightly worse by the interaction between the relevant disablement (i.e. that which is caused by the vaccine) and the new disablement (i.e. that which is not caused by the vaccine). The relevant disablement is therefore slightly greater in the presence of the new condition compared to before the new condition occurred.

In this situation, a small interaction addition may be made to the relevant disablement to account for this. The interaction addition does not represent the whole disablement from the new condition that has occurred post vaccine, but rather is for the interaction only between the new condition and the disablement relevant to vaccination (the interaction addition). This interaction addition usually represents only a small additional disablement.

4.2.6 The final disablement assessment value should be advised as a percentage or small range of percentages and fully justified with a statement of whether the threshold for severe disablement is reached.

4.3 Comparators

Assessment of the level of disablement is carried out, and stated to be, in accordance with Section 103 of the Social Security Contributions & Benefits Act 1992 – Disablement Benefit Legislation. An example of 60% disablement from Schedule 2 of the General Benefit Regulations - The Social Security (General Benefit) Regulations 1982 statutory percentages must be given for comparison.

4.3.1The assessment must compare the individual to a person of the same age and sex in whom physical and mental condition is normal and this phrase must be stated in the report.

4.3.2Useful reference materials:

Schedule 2 of the General Benefit Regulations - [The Social Security (General Benefit) Regulations 1982 (legislation.gov.uk)](https://www.legislation.gov.uk/uksi/1982/1408/schedule/2)

* Appendix 1 – extract of Non scheduled assessments (IIDB Handbook March 2021)
* Appendix 2 – extract of Mental Health assessment Advice (IIBD Handbook March 2021)
* Appendix 3 – extract of Suggested Levels of Disablement for Respiratory Prescribed Diseases from DWP Respiratory Prescribed Diseases Handbook (May 2021)

4.3.3 Other disablement scales should not be used as they are not necessarily comparable to Schedule 2 of the General Benefit Regulations - [The Social Security (General Benefit) Regulations 1982 (legislation.gov.uk).](https://www.legislation.gov.uk/uksi/1982/1408/schedule/2)

4.4 Aids and Prostheses

These must be considered in assessment of disability and disablement.

The scheduled assessments reflect loss of function and loss of tissue; however, they take into account the use of suitable aids/appliances/prosthesis. Therefore, a person who cannot make use of an appropriate aid/appliance/prosthesis due to reasonable causes may be more functionally disabled and the disablement should reflect this. The scheduled assessments (Schedule 2 of the General Benefits Regulations 1982) serve as a guide and conditions such as pain or unstable joints may result in a greater level of disability and disablement. Detailed justification of any advice given is essential.

4.5 Disablement at the time of assessment

The assessors must indicate in the report whether the level of disablement is currently 60% or more, according to the most up to date available evidence. In some cases, the level of disablement may have reduced since the height of the condition.

4.5.2 Claimants who were at least 60% disabled but have already somewhat recovered and are no longer considered  to meet the 60% disablement threshold.

Assessors are required to consider all relevant factors when determining whether a person meets the necessary 60% disablement threshold, including the period of time that the person has been disabled and may be expected to remain disabled due to the vaccine. Where a Claimant who, at the time of the assessment has recovered to below 60% or is recovering  from a disability and the assessor concludes that, on the balance of probabilities, the future prognosis does not lead to the 60% threshold being met, the claim should be rejected.  All claims should be assessed at the earliest available opportunity once medical records have been collected and assessment capacity is available.

The VDPS assessment of disablement looks over a period of time during which the claimant has suffered and is expected to suffer, based on all of the medical evidence available and not just the disablement on a particular date in time. This means that in some cases, even where there have been serious short-term symptoms, over the whole period of assessment it may be that the disablement does not meet the 60% threshold. This means that in some cases, even where there have previously been serious symptoms, over the whole period of assessment it may be that the disablement does not meet the 60% threshold.

**4.6 Future Disablement**

Future prognosis must be considered during the assessment, and the report must indicate whether the level of disability is likely to reach and remain at or above 60% or not in the future when compared to a person of the same age and sex with normal physical and mental condition.

4.6.1 Future Improvement

If the condition is likely to improve on balance of probabilities, a clear and robust justification for this advice must be given with sources of evidence quoted.

4.6.1.1Claimants who are at least 60% disabled but who are expected to recover to the point where they are no longer 60% disabled**:**

The legislation (and case law resulting from that legislation) requires that the assessments consider the length of time a person has been disabled and may be expected to continue to remain disabled due to the vaccine in decisions about whether or not they meet the necessary 60% disablement threshold. Assessors should be looking at the Claimant’s future prognosis, on the balance of probabilities, when determining the extent of the disablement. Where a disability is likely to improve after what might be considered a short period of time, 12 months might be considered a “reasonable period” for consideration, this can be factored into a determination of whether the threshold is met for the necessary 60% disablement, although 12 months is not a definitive cut off point per se.

Any unsuccessful claimant who experienced an unexpected or unforeseen deterioration, or failure to recover as anticipated, would be able to request a “reversal” of the outcome of their case under the VDPA – effectively meaning that the case is reassessed.

4.6.2 Future Deterioration

If a condition is likely to deteriorate, this must be stated with appropriate references quoted.

4.6.2.1Claimants who are not currently 60% disabled but are likely become 60% disabled in the future (particularly common for children receiving vaccinations):

Claims should be awarded in circumstances where the assessor concludes that the necessary 60% disablement threshold is crossed having taking into account all relevant factors, including the Claimant’s future prognosis (across the period of time that the person has suffered and may be expected to continue to suffer from the disability), even if the claimant is not considered 60% disabled at the point of assessment, as per the Court of Appeal judgment in SSWP v FG (John) [2017] EWCA Civ 61.

**4.7 Advising causation and disablement in posthumous cases**

The Vaccine Damage Payment Act 1979 (VDPA) states that, subject to the fulfilment of conditions of entitlement being met, a payment shall be made if a person is, or was **immediately before his death**, severely disabled as a result of vaccination against any of the diseases to which this Act applies.

 4.7.1 Causation is assessed in accordance with the principles of VDPS above. Where causation is accepted, the following process is followed in relation to assessing disablement.

4.7.2 Disablement assessment:

* Loss of faculty is stated.
* Reference to the Schedule 2 assessments is stated.
* An example of a 60% disablement from the Schedule 2   Regulations is quoted.
* Comparison is made to a person of the same age and sex.

4.7.3 Where the vaccine has, on the balance of probabilities, caused the death of the claimant.

* It is stated that disablement caused by the vaccine exceed the 60% threshold at or immediately before death.
* It is not a requirement to ascribe a specific percentage to death.

4.7.4 Applying an offset in a posthumous case.

4.7.4.1 Where a claimant dies from an unconnected condition, but in the presence of a disability caused by the vaccine, then the relevant disablement assessment is completed according to the principles of the VDPS as stated above.

4.7.4.2 Where an offset is required for a preexisting disability, but the relevant disablement (i.e. that which is caused by the vaccine) has caused the death of the claimant, then a justification is given to explain that after taking into account any required offset, the relevant disablement caused by the vaccine exceeds the 60% threshold.

**5. Outcome Report**

The standards expected within the VDPS medical assessment reports cover three key Quality Themes.

1. **Presentation and process**
2. **Medical Reasoning**
3. **Professional Issues**

**5.1 Presentation and process**

* Standard template for the outcome report must be used.
* All required Sections of the outcome report template must be completed correctly.
* Beginning of Part 1 should be completed following the completion of the assessment to indicate either:
  + Claim is disallowed:
    - On the balance of probability, causation has not been accepted.
    - On the balance of probability, causation has been accepted but disablement due to vaccination is less than 60%.
  + Award is to be made:
    - on the balance of probability, the person named is and is likely to remain severely disabled as a result of vaccination.
    - on the balance of probability, the person named is not severely disabled currently but is more likely than not to become severely disabled as a result of vaccination.

* The assessor must review all evidence in the file and record the number and type of documents at Section1.
* The report must be appropriately referenced. Where the report contains information from the file, the document numbers must be given. Opinions and conclusions must be justified with appropriate references.
* Reports must be legible and clearly presented with grammar and spell checks applied.
* Reports must be written in plain English with medical jargon and abbreviations avoided or explained such that the report can be read and understood by a non-medical person. Reports will be shared with the claimant.
* The report must confirm that the relevant vaccine or vaccines have been given and the date of administration must be stated. In the case of Covid-19 vaccines, the manufacturer (if known) must be recorded in the report.
* The history from the claimant/claimant’s representative must be recorded at Section 2 with the main condition or conditions assessed as part of the medical assessment clearly stated and a comprehensive account given of the nature of the stated claim.
* Responses should be given to all questions raised in the claim and on documentation sent by NHSBSA.
* Presence or absence of significant family history should be recorded at Section 2. Identifiable 3rd party information will not be included. Terms such as relative or family member will be acceptable.
* Comprehensive medical history from the medical evidence should be given in chronological order at Section 2 including in all relevant past medical history. Any significant past medical history that is not relevant to the claim can be listed under a separate heading of Past Medical History at Section 2. Professional judgement should be exercised to ensure that sensitive past medical history is not included unless necessary for progression of the claim. If there is no past medical history, this must be documented.
* Consistency will be maintained throughout the report or a thorough explanation will be given in relation to any inconsistencies.
* The presence or absence of symptoms at the time of vaccination, and history of the onset of relevant symptoms must be recorded.
* It will be confirmed in the report that the relevant vaccine or vaccines have been given and the date of administration  recorded in the report. In the case of Covid-19 vaccines, the manufacturer will be recorded in the report.

**5.2 Medical Reasoning**

**Causation**

* Causation advice will be given on the balance of probability, and this will be stated in the report.
* Advice will be adequately justified. This requires that the author of a report gives a clear explanation of the reasons for giving certain advice and the underlying evidence by which they were guided.
* There will be a clear explanation of medical issues such that the report can be clearly understood by a non-medical person. Any underlying medical reasoning and all medical terms will be clearly explained the first time they are mentioned in the report.
* The report will be appropriately detailed with adequate information to give robustly justified advice on causation.
* Comprehensive medical reasoning will be documented to support the advice on causation and will be in keeping with the consensus of informed medical opinion.
* References used will be   independent, current, credible, robust sources of medical evidence and will be stated in the report.
* Discrepancies will be addressed, and an explanation given for why one piece of evidence has been favoured over another.

**Disablement**

* Where there is disablement caused by the vaccine, the loss of faculty and the disability will be specified in the report.
* Disablement will be compared to a person of the same age and sex in whom physical and mental health is normal.
* Disablement advised wil be stated as being in accordance with Schedule 2 of The Social Security (General Benefit) Regulations 1982, with examples of statutory percentages given for comparison, including an example of a disablement equivalent to 60%.
* Where causation has been accepted, all relevant disablement (i.e. disablement caused by the vaccine) will be considered. This may include impaired function of several different parts of the body and may require an addition for any relevant deterioration of mental health. This process will be evident in the report.
* Any pre-existing disablement of the same body functions will be taken into account and any necessary deductions explained, giving a final net assessment which is fully relevant to the vaccine being assessed.
* An assessment value will be advised as a percentage or small range of percentages and fully justified.
* A statement of whether the threshold for severe disablement is reached will be included in the report.
* Consideration of the future disablement will be recorded, and advice given regarding whether or not the 60% threshold is likely to be met in future.
* Where causation is not accepted, disablement advice in Section 7 will not be required.

**5.3. Professional Issues**

* No confidential third-party information will be included in the report.
* The report will contain evidence that the author has used adequate information (including the medical file and other credible sources) to produce well justified advice.
* Any concerns that are identified during the assessment should be reported to NHSBSA. This may include, but not limited to, sensitive information, harmful information, safeguarding concerns, or where incorrect patient records have been included within the claimant’s records from healthcare providers.

**6. Peer Review**

Every VDPS Outcome report will be peer reviewed by experienced VDPS medical assessors who has responsibility to ensure the overall quality of the report and that all credible sources of evidence are appropriately and consistently applied. The peer reviewer will exercise professional curiosity and ensure all aspects of the report and referenced materials are considered to ensure the assessment is fair, objective, comprehensive and accurate. The peer reviewer will ensure all information is accurate and consistent throughout the whole report and every reference is relevant and credible.

Once the review is complete the peer reviewer will be in the position to sign off the report and professionally agree to the full content.

**7. Audit**

7.1 A selection of reports will be quality assured by NHSBSA and measured against the principles and standards expressed in this document. This is to ensure that the principles are consistently and appropriately applied.

7.2 An Integrated Quality Assurance (IQA) form will be completed by NHSBSA with feedback given where required. The feedback will be returned to the provider clearly indicating any issues requiring further attention and whether any amendments to the report are suggested for consideration. The Provider will share the feedback with the original author and any other practitioners involved in the peer review of the report. Relevant amendments should be made by the author and checked by the peer reviewer before the report is returned to NHSBSA with all amendments clearly indicated.

7.3 The report will be graded as follows:

**Acceptable** - Essential requirements are met to the extent that the report fully conforms to the principles included in this document.

**Minor issues** - Essential requirements are adequately satisfied. However, specified improvements would enhance the quality and understanding of the report.

**Significant issues** -   Essential requirements are not met to the extent that the report fails to meet the NHSBSA Quality Standard and may negatively impact the credibility of service.

**8. Request for Reversal**

If the claimant considers the determination to be incorrect (in terms of causation, or level of current or future disablement), they can request that the decision is reviewed**.** The claimant must provide an explanation of why they believe the original decision to be wrong and may provide further  evidence to support their request.

8.1Such cases will be referred to medical assessors for consideration of a formal review

 of the case.

8.2Where a formal review is indicated, the medical assessor must consider the claim in light of the new evidence and advise the NHSBSA whether the advice and/or outcome of the original assessment is affected.

8.2.1In reconsidering the claim, all aspects can be reconsidered including eligibility, causation and disablement irrespective of the nature of the request and new evidence.

8.2.2 An objective and comprehensive report must be provided on the appropriate VAD82 form.

8.3 If the new information does not meet the requirements for a reconsideration, the reasons for this will be explained on the appropriate form.

**9. Appeals**

Where an initial claim for Vaccine Damage Payment has been rejected (on grounds of causation or disablement) and following the reversal review the outcome remains unchanged, claimants have the right to an appeal of the disallowance of their claim, by a First-tier Tribunal (Ft-T) under Section 4 of the Act.

9.1 The Tribunal is comprised of a legally qualified chairman and 1 or 2 medical members.

9.2 There is no time limit imposed for making such an appeal request under Section 4 of the Act.

9.3 Section 3A of the VDPA allows a decision made by a Ft-T to be reviewed by the Secretary of State or to be taken to the Upper Tribunal.

9.4 A judicial review on a point of law can be carried out in the Administrative Court (part of the High Court).

9.5 Appeals may require additional input from the assessor to clarify factual aspects of their report and support responses to appellant questions.

**Appendices**

This section includes other external resources that the independent medical assessor may use to support their assessment. We’ve cited the source of each one.

**Appendix 1 – Non scheduled assessments**

Source: An extract from ‘IIB Handbook 1 for Health Care Professionals The Principles of Assessment v 13, March 2021’

(Note: Not all information may be directly applicable to Vaccine Damage assessment.)

**Limb amputation cases**

**Assessment**

The prescribed degrees of disablement set out in the Schedule relate to stabilised degrees of disablement. The HM Courts and Tribunals Service generally give a scheduled assessment where the claimant has a healed stump, has been fitted with an artificial limb, and has had a reasonable amount of time to get used to it. Where this is not the case, a provisional assessment at a higher rate than the scheduled assessment should normally be given.

**Non Scheduled Assessments**

The following information refers to guidance on levels of assessments commonly used by the HM Courts and Tribunals Service for ankyloses in the optimum positions. These are often referred to as the Non Scheduled Assessments. While the Non Scheduled Assessments do not carry the full authority of legislation, they are useful benchmarks for use by an HCP when considering a non-scheduled injury.

In assessing the disablement resulting from the complete fixation of joints, consideration needs to be given to the position in which the joint is fixed.

Below are listed the usual optimum positions for ankylosed joints:

**Shoulders**: Arm abducted to about 20 degrees with the elbow slightly in   front of the body and with free movements of the shoulder girdle.

**Elbow:** The angle between humerus and forearm should be rather more than a right angle, at about 110 degrees. The forearm should be supinated, so that the palm is slightly upwards.

**Wrist:** **Wrist:** In the neutral position, that is in line with the forearm and with slight or no loss of pronation and supination

**Hip:** **Hip:** Thigh flexed 10 degrees with a slight abduction and slight   external rotation

**Knee**: In 5 degrees of flexion

**Ankle**: 5-10 degrees plantar flexion of the foot

The following table notes the type of assessments for ankyloses, in the optimum positions, which have been given by the HM Courts and Tribunals Service. However, the HCP should advise on the appropriate disablement for the individual claimant, based on functional restriction when compared to a person of same age and sex whose physical and mental condition is normal.

**Ankyloses in the Optimum Position                                           Per Cent**

Shape

Shoulder 40 %

Elbow 40 %

Wrist 30 %

Hip 60 %

Knee 30 %

Ankle 20 %

Shape

**Flail joints**

Where there is abnormal mobility, the assessment given by the HM Courts and Tribunals Service for the lower limb has normally been at a higher rate that the ankylosed joint. Improved function may sometimes be achieved in both flail and partially ankylosed joints by skilled orthopaedic treatment.

**Injuries to hands**

In considering injuries to hands, it is the resulting overall loss of ability to do what a person of the same age and sex, whose physical and mental condition is normal, would be able to do which is to be assessed. Where a claimant has sustained two or more injuries, specified separately in the Schedule, disablement is not necessarily an aggregate of specific figures in the Schedule.

To avoid confusion resulting from the use of "first, second and third, etc." when referring to fingers in medical reports, the terminology, "thumb, index, middle, ring and little finger" should always be used.

**Disfigurement**

In assessing face and scalp injuries, the factor of disfigurement is important.

**Hysterical conditions**

Where there is no organic explanation for symptoms, the cause may well be a mental loss of faculty. It is for consideration whether such mental loss of faculty is relevant or whether, for instance, it is a conscious or deliberate mental state that is clearly not the result of the relevant Industrial Accident. Where it is an unconscious or uncontrollable functional condition, the question arises as to whether the relevant Industrial Accident is an effective cause of that mental state. However, it may be that the Industrial Accident was merely the occasion upon which the mental state, which was already present or would by the date of the assessment, in the absence of the Industrial Accident, have manifested itself.

**Assessments for eye injuries**

Items 4, 32 and 33 of the Schedule 2 of the General Benefit Regulations apply to injuries to the eyes. It is important that HCPs record the visual findings for both eyes showing visual acuity figures both before and after correction. See Section 1 of Handbook for Upper Tribunal Judge’s ruling on artificial aids.

Where an Industrial Accident results in an injury to one eye (previously normal) but the vision in the uninjured eye is already impaired, the disablement resulting from the relevant Industrial Accident may be calculated in the following way:

*The degree of disablement is assessed taking both eyes together and where applicable subtracting the degree of disablement in both eyes that would have been present in the period under consideration if the relevant Industrial Accident had not occurred. Partial (P) relevance with an offset and an O(Pre) or O(Post) condition may be appropriate.*

The Valuation Table (provided overleaf) reproduced from the Report on the 18th International Congress of Ophthalmology (1958) may be of assistance to HCPs considering defective vision.

Valuation Table for Reduction of Vision: Compensation Rates (Figures in percentages) [reproduced from Report of the 18th International Congress of Ophthalmology, 1958]

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | 6/6 | 5/6 | 6/9 | 5/9 | 6/12 | 6/18 | 6/24 | 6/36 | - | 6/60 | 4/60 | 3/60 | - |
|  |  | 1/0.9 | 0.8 | 0.7 | 0.6 | 0.5 | 0.4 | 0.3 | 0.2 | 0.15 | 0.1 | 1/15 | 1/20 | -1/20 |
| 6/6 | 1/0.9 | 0 | 0 | 2 | 3 | 4 | 6 | 9 | 12 | 16 | 20 | 23 | 25 | 27 |
| 5/6 | 0.8 | 0 | 0 | 3 | 4 | 5 | 7 | 10 | 14 | 18 | 22 | 24 | 26 | 28 |
| 6/9 | 0.7 | 2 | 3 | 4 | 5 | 6 | 8 | 12 | 16 | 20 | 24 | 26 | 28 | 30 |
| 5/9 | 0.6 | 3 | 4 | 5 | 6 | 7 | 10 | 14 | 19 | 22 | 26 | 29 | 32 | 35 |
| 6/12 | 0.5 | 4 | 5 | 6 | 7 | 8 | 12 | 17 | 22 | 25 | 28 | 32 | 36 | 40 |
| 6/18 | 0.4 | 6 | 7 | 8 | 10 | 12 | 16 | 20 | 25 | 28 | 31 | 35 | 40 | 45 |
| 6/24 | 0.3 | 9 | 10 | 12 | 14 | 17 | 20 | 25 | 33 | 38 | 42 | 47 | 52 | 60 |
| 6/36 | 0.2 | 12 | 14 | 16 | 19 | 22 | 25 | 33 | 47 | 55 | 60 | 67 | 75 | 80 |
| - | 0.15 | 16 | 18 | 20 | 22 | 25 | 28 | 38 | 55 | 63 | 70 | 78 | 83 | 88 |
| 6/60 | 0.1 | 20 | 22 | 24 | 26 | 28 | 31 | 42 | 60 | 70 | 80 | 85 | 90 | 95 |
| 4/60 | 1/15 | 23 | 24 | 26 | 29 | 32 | 35 | 47 | 67 | 78 | 85 | 92 | 95 | 98 |
| 3/60 | 1/20 | 25 | 26 | 28 | 32 | 36 | 40 | 52 | 75 | 83 | 90 | 95 | 98 | 100 |
| - | -1/20 | 27 | 28 | 30 | 35 | 40 | 45 | 60 | 80 | 88 | 95 | 98 | 100 | 100 |

NOTE: These assessments are for defective vision without special features and are based on the visual defect measured, after correction with glasses by the ordinary test only.

The method of assessment of defective vision is based on the Valuation Table referred to above. Any greater disablement arising from interaction with a disability in the eye not involved in the Industrial Accident is automatically included. The following fictitious examples that have regard only to visual acuity and assume no additional features such as pain or disfigurement illustrate this method of calculation.

Example 1: Claimant sustains injury to the right eye (vision normal before Industrial Accident) which results in corrected visual acuity of 6/18. The left eye has no effective corrected vision because of a pre-existing condition.

Impaired vision "P" relevant

Defective left eye O(Pre) (other effective cause)

Assessment for both eyes

(right 6/18, left Nil)             45%

Assessment for

pre-existing defective

vision (right 6/6, left Nil)             27%

Net assessment 18% (45% offset 27%)

Example 2: Claimant sustains injury to the right eye that results in corrected visual acuity of 6/24. Prior to the Industrial Accident right and left visual acuities each corrected to 6/12.

Impaired vision "P" relevant

Defective vision in both eyes O(Pre) (other effective cause)

Assessment for both eyes

(right 6/24, left 6/12)                           17%

Assessment for pre-existing

Defective vision

(right 6/12, left 6/12) 8%

Net assessment                                  9% (17% - offset 8%)

**Aphakia and Pseudophakia**

HM Courts and Tribunals Service have normally taken account of the degree of tolerance and sensitivity to the wearing of a contact lens in assessing the degree of disablement.

Industrial injuries involving the eyes may result in aphakia or pseudophakia which may be unilateral and bilateral.

In aphakia there is absence or loss of the natural lens of the eye, for example following surgical removal of the lens in cataract surgery.  The individual may be given thick pebble cataract spectacles or contact lenses to correct the visual acuity. In the majority of cases, treatment gives rise to pseudophakia (false lens), where the damaged lens is removed and a plastic intraocular lens is inserted.

All of these treatments have drawbacks. Spectacle lenses produce a reduced visual field and there is considerable distortion. Contact lenses can be inconvenient, require a degree of manual dexterity and can be difficult to manage particularly if near vision is considerably reduced. Intraocular lenses provide a fixed focus and loss of accommodation.

**Note**: the following reflects the consensus of opinion of the Ophthalmologist members of the HM Courts and Tribunals Service.

**Assessment of Disablement in Aphakic and Pseudophakic Eyes**

1. Determine the best corrected visual acuity for each eye separately

2. Assess visual disablement according to the “Reduction of Vision: Compensation Rates” table

3. Add the appropriate figure as shown overleaf

**Note**: there may be additional factors, which may lead to a higher assessment such as, cosmetic disfigurement of the eye. The individual must be compared with a person of same age and sex whose physical and mental condition is normal. Loss of accommodation in a young person would be more disabling than that in a person in the age group in which presbyopia is a normal feature.

**Unilateral Aphakia**

Spectacle lenses 9%

Contact lenses 6%

**Bilateral Aphakia**

Spectacle lenses  22%

Contact lenses                                        16%

**Pseudophakia**

Unilateral                   3%

Bilateral                                                         8%

**Deafness**

The scheduled assessment for absolute deafness is 100 per cent. The pages overleaf include, for the information of HCPs, a note of assessments for other degrees of deafness, which have been given in the normal Industrial Accident case by the HM Courts and Tribunals Service. It should be noted that in the case of PD A10 (Occupational Deafness), disablement is assessed using the table of binaural disablement. The binaural table must not be used for the purpose of assessing disablement when the deafness is as a result of an Industrial Accident.

**Indicative disablement for non-scheduled assessments given by the HM Courts and Tribunals Service for deafness due to Industrial Accidents only:**

**Degree of hearing attained** **with both ears together**

Shape

Shout not beyond 1 metre 80 %

Conversational voice not over 30 cms 60 %

Conversational voice not over 1 metre 40 %

Conversational voice not over 2 metres 20 %

Conversational voice not over 3 metres:

(a) one ear totally deaf 20 %

(b) otherwise Less than 20 %

Shape

**Notes on assessments for deafness**

Where the hearing in one ear is normal, complete deafness in the other affects the detection of the direction of sound and decisions of the HM Courts and Tribunals Service indicate a minimum assessment of 20 % is reasonable.

A case in which the right ear heard a conversational voice at 2 metres (6 feet), the left ear a conversational voice at 30 cms (1 foot) and both ears together a conversational voice at 1 metre (3 feet), should therefore be recorded as:

Right Conversational Voice 2 metres

Left Conversational Voice 30 cms

Right and Left Conversational Voice 1 metre

Assessment of disablement 40%

The assessments given above apply to the deafness only. Any additional factors such as vertigo, tinnitus or chronic suppuration may warrant an addition to the assessment of disablement. If so, this should be made clear in the HCP’s report.

**Assessments involving loss of tissue**

**Splenectomy**

Increasing evidence shows that the removal of the spleen may lower natural resistance to certain organisms and removal of the spleen also involves loss of tissue.

HM Courts and Tribunals Service having taken these factors into account have assessed the degree of disablement resulting from the removal of the spleen at between 2% and 5%.

**Orchidectomy**

The removal of a testicle involves tissue loss and loss of reserve useful function which constitutes a small permanent loss of faculty. HM Courts and Tribunals Service have assessed the degree of disablement resulting from the removal of a testicle at between 2% and 5%.

**Nephrectomy**

The Upper Tribunal Judge held in decision R(I)14/66 that where a person loses a kidney then as a matter of law it must necessarily mean that there is a loss of faculty. The extent of disablement resulting from that loss of faculty is for the medical authorities to give advice on and in this respect regard must be had to the loss of reserve useful function. Where the other kidney is functioning normally HM Courts and Tribunals Service have assessed the degree of disablement at between 5% and 10 %.

**Appendix 2 – Assessments of Mental Health Disablement**

Source: An extract from ‘IIB Handbook 1 for Health Care Professionals The Principles of Assessment v 13, March 2021’

(Note: Not all information may be directly applicable to Vaccine Damage assessment.)

**Assessments of Mental Health disablement**

Disability from mental health conditions resulting from an Industrial Accident or PD rarely continues indefinitely, so it would be unusual to advise a life award. Assessments below 14% should be to a date final; those above 14% should be provisional, with the expectation of subsequent improvement. What follows is a guide to the assessment of disablement resulting from mental health conditions.

**Normal mental health/Virtually no disablement**

Good mental/psychological functioning in social and occupational environments.  Interested in a wide range of activities.  Socially effective in everyday life.  No evidence that he/she would not be effective in an occupational environment.  No more than everyday problems or concerns – if these provoke symptoms they are mild and fleeting and do not disrupt day-to-day functions.

**Minimal Problems**

No more than slight impairment of mental functioning in social environments.  Has meaningful interpersonal relationships.  Minor changes in an environment may be necessary to limit provocation of some mild symptoms (e.g. mild anxiety, depressed mood, mildly anti-social behaviour) which are transient self-limiting or adequately controlled by psychotropic medications, psychotherapy or counselling.

**Very Mild Problems**

Slight impairment of mental functioning in social environments.  Functions reasonably well in an occupational environment suited to present skills, educational attainments and work experience, but modest changes to the occupational environment may be required, such as avoidance of tight deadlines.  Clear control of activities to limit provocation of mild symptoms e.g. mild anxiety, irritability, depressed affect and antisocial behaviour, mild insomnia.  May have increased alcohol and/or tobacco consumption if claimant is a drinker and/or smoker.  Disturbances of appetite or eating disorders may occur.  May repeatedly check on trivial matters, e.g. taps are turned off, washing hands several times before meals.

**Mild Problems**

Mild symptoms e.g. anxiety, occasional panic disorders, depressed or flat mood which are exacerbated by psychosocial stressors.  Tense and irritable.  Repeatedly checks trivial matters e.g. that taps are turned off, thereby interfering with social and occupational activities.  Functions reasonably well in an environment tailored to limit common stressors.

May have some difficulty with attendance at work (e.g. more short-term periods of incapacity than normal).  Decision making usually competent.  Has some meaningful interpersonal relationships, but has few friends and can have difficult relationships with peers or co-workers.  Interests outside of work and in hobbies may wane.

Disturbances in appetite or eating disorders may occur interfering with social activities.  Insomnia may be a problem.

**Mild to Moderate Problem**

Moderate symptoms e.g. flat affect, circumstantial speech, occasional panic attacks, mood swings.  Very few or no friends.  Conflicts with peers and co-workers and some unresolved conflicts but these do not disrupt family and social functioning.  Some emotional blocking or tension is evident, but decision is usually competent.  Some anti-social behaviour, unexplained absences from work.  Few leisure interests and hobbies.

**Moderate Problems**

Likely to have difficulty functioning in many social and occupational environments, e.g. has no friends.  Emotionally labile.  Anti-social behaviour, obsessional rituals.  Avoids outings and gatherings.  Few, if any, hobbies or leisure activities.

Decision making intermittently competent and effective.  Remunerative work likely to be possible only in a highly structured supportive and supervised environment.  Frequent unexplained absences from work.

**Moderately Severe Problems**

Behaviour considerably influenced by delusions/hallucinations or serious impairment in communication/judgement.  May act grossly inappropriately and may have suicidal preoccupations.  Decision making quite ineffective.  Problems relating to others.  Infrequent periods of enjoyment of life.  Frequent distancing from others or open hostility.  Serious impairment in judgement/thinking/mood.

**Severe Problems**

Some danger of hurting self e.g. suicidal preoccupation or suicide attempts without clear expectation of death.  Preoccupied with suicidal thoughts.  Major impairment in maturation/commitment due to the effects of mental illness manifesting in behaviour such as failure to maintain personal hygiene, failure to care for children.  Major impairment of social and occupational functioning, e.g. cannot keep a job, stays in bed all day, anti-social behaviour.  Ineffective anger and/or emotional deadness which interfere with family or well being.  Day to day life disturbed by delusions or hallucinations or obsessional rituals, other symptoms of major psychiatric illness resulting in substantial impairment of communication or judgement.

**Very Severe Problems**

Persistent danger of severely hurting self e.g. risk of self harm or suicide with a clear expectation of death (as opposed to cries for help). Despair and cynicism are pervasive. Persistent danger to others e.g. persistent violence, family members in danger. Persistent inability to care for personal hygiene etc. Generally painful interpersonal conflicts. Open hostility evident in relationships and attitudes. No sense of commitment or attachment. Communications grossly impaired, e.g. mute or largely incoherent.

**Appendix 3 – Suggested Levels of Disablement for Respiratory Prescribed Diseases**

Source: Extract of DWP Respiratory Prescribed Diseases Handbook (May 2021)

The information provided is not binding in any way and carries no prescriptive status for either the RPD HCP or the DM. It is purely advisory and used only in the context of a full and careful disability assessment. There may be instances in which, for very cogent medical reasons, a disablement is advised which does not conform to these bands because of other medical factors relating to the case, including the specific RPD present, any comorbidity, response to management, etc . Each case has to be considered on its own merit.

|  |  |
| --- | --- |
| **ASSESSMENT BAND** | **HISTORY, MEDICATION, CLINICAL FEATURES, INVESTIGATIONS**  **(These may vary according to specific RPD under consideration and any additional associated features)** |
| Minimal  (1 – 5%) | May have none or few symptoms and/or functional limitations. May have no breathlessness even on exertion.  May be on no medication.  May have none or early clinical signs.  May have early radiological findings.  FVC >80%  FEV1 >80%  Hospital measured predicted gas transfer likely to be within normal range ( DLco >70%) |
| Very mild to mild  (6 – 10%) | May have few symptoms and/or functional limitations. May be breathless on prolonged or heavy exertion.  May be on no or simple medication.  May have none or early clinical signs.  Radiological findings present.  FVC 70 – 79%  FEV1 70 – 79%  May have reduced or normal hospital measured predicted gas transfer (DLco 60% to >70%) |

|  |  |
| --- | --- |
| Mild to moderate  (11 – 30%) | May have some symptoms and/or functional limitations. May be breathless walking uphill or climbing stairs, on hurrying on level ground, or walking on level ground at normal pace for age.  May be on regular medication.  Clinical signs may be present.  Radiological findings present.  FVC 60 – 79%  FEV1 60 – 79%  Reduced or normal hospital measured predicted gas transfer (DLco 60% to >70%) |
| Moderate to moderately severe  (31 – 50%) | Variable level of symptoms and/or functional limitations may be present.  May be breathless on walking 100 m at normal or slow pace, or climbing one flight of stairs at normal or slow pace.  May be receiving specialist care.  Likely to be on regular medication.  Clinical signs may be present.  Radiological findings present.  FVC 50 – 59%  FEV1 40 – 59%  Reduced hospital measured predicted gas transfer (DLco 40 – 59%)  (Remember that 50% rule for COPD might apply in PD D1) |
| Severe  (51 – 80%) | Variable level of symptoms and/or functional limitations may be present. Breathlessness may prevent walking 100 m at slow pace without stopping, climbing one flight of stairs without stopping, or activity outside the home without assistance or supervision. Breathlessness may limit activities to within the home.  May be receiving specialist care.  Likely to be on regular medication. May be on occasional oxygen.  Clinical signs present, which may be advanced.  More extensive radiological findings present usually showing more extensive disease.  FVC <50%  FEV1 <40%  Reduced hospital measured predicted gas transfer (DLco <40%)  (Remember that 50% rule for COPD might apply in PD D1) |
| Very severe  (81% or more) | Significant symptoms and/or functional limitations may be present. May be able to walk only a few steps because of breathlessness. May be bed and chair bound, and totally dependent on carers because of breathlessness.  May be receiving specialist care.  On regular medication, may consist of multiple drug regimes. May be on occasional or regular oxygen.  Clinical signs present, which may be advanced.  Extensive radiological findings present.  FVC < 50%  FEV1 <40%  Reduced hospital measured predicted gas transfer (DLco <40%)  (Remember that 50% rule for COPD might apply in PD D1) |