Atlas of MS – 3rd Edition - TOPICAL QUESTIONS 2022
Usage and affordability of disease modifying therapies (DMTs) and the Expanded Disability Status Scale (EDSS)
6-4-22 (final)

COUNTRY: Please indicate the country you are providing data for:

WHO REGION: Please indicate the WHO (World Health Organization) region your country belongs to. If you are unsure please look up your country here: https://docs.google.com/spreadsheets/d/1flcSd2SF-uS6rslSVCIDIn6NbPLZ6S-I9VDu8LxRZbU/edit?usp=sharing. This information can also be found in your email invite.
1. Africa
2. Americas
3. Eastern Mediterranean
4. Europe
5. South-East Asia
6. Western Pacific

WORLD BANK INCOME: Please indicate the World Bank Income level your country belongs to. If you are unsure please look up your country here: https://docs.google.com/spreadsheets/d/1flcSd2SF-uS6rslSVCIDIn6NbPLZ6S-I9VDu8LxRZbU/edit?usp=sharing This information can also be found in your email invite.
1. High Income
2. Upper Middle Income
3. Lower Middle Income
4. Low Income

CONSENT

This survey is conducted by the MS International Federation (MSIF). The purpose of the survey is to collect information for the Atlas of Multiple Sclerosis (MS). The Atlas is a key tool for organisations, health professionals and individuals when advocating for better access to treatment, care and support, and has been widely cited in the research literature.

Your participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time.

Your personal data may be used by MSIF in relation to the Atlas project (for example for validation purposes, invitations to participate in future updates, advice or reporting etc.).

MSIF take the duty to protect your personal information seriously. Any personal information you provide will be collected, transferred and/or stored in compliance with MSIF's privacy policy https://www.msif.org/privacy-policy/. We will retain this information for the duration of the Atlas project. The data that we collect from you may be transferred to, and stored at locations both inside or outside the European Economic Area ("EEA") or Switzerland, including the USA.

To agree to the above terms and conditions and proceed with the survey please select "I agree" below:
1. I agree
2. I do not agree

INTRODUCTION

Thank you for agreeing to contribute data to the Atlas of MS - you are part of a global movement to create this important data source that will be used to improve the situation for people with MS worldwide. We cannot do this without you!

When answering the questions in this survey, please focus on Multiple Sclerosis (MS) only. Please do not include other demyelinating conditions such as Neuromyelitis Optica (NMO).

It is important that the answers provided are as accurate as possible. To help with validation and interpretation some questions ask for sources of evidence for the data. However, we appreciate that you may not have evidence to support the answer - for these, it would be useful to consult with others in the country to ensure confidence in the answers and that best estimates are provided for the country (so they are not just based on one person's opinion). To help with the collaboration we have provided a PDF version of the survey that you can use to share and discuss with colleagues or collect data from multiple sources before inputting the data into the online survey.

However, we appreciate that some of the questions may be difficult to answer or evidence and, if you do not know the exact answer, we would like to know **your best estimate**. If you really cannot provide an estimate then it is fine to leave that particular question blank.

Once you have started completing the questionnaire, all entered data will be saved as you go, so it is possible to pause and return to it at a later time.

CONTACT DETAILS: Please provide the contact information for **the lead person** completing this questionnaire and coordinating the response for the country. There is space to include additional collaborators at the end of the questionnaire.

By providing this information, you are consenting for MSIF and their trusted partners to securely hold this data for the duration of the Atlas project and to contact you in connection with the project.

Full Name:	
Title (Dr, Prof, Mr, Ms. etc…):	
Current Position/job title:	
Organization:	
Email:	

Please select ONE option that best describes the role of the lead person completing this questionnaire and coordinating the response for the country.
1. Clinician/other health professional/Researcher
2. Employee or volunteer for an MS society
3. Person with or affected by MS
4. Another role

Disease modifying therapies (DMTs)

The next few questions are to understand the numbers of people with MS in the country currently treated with disease modifying therapies (DMTs) and which types of DMTs they are treated with, as well as the affordability of each type of DMT.

A disease modifying therapy (DMT) is a treatment or drug that can modify the course of MS by reducing the number of relapses or slowing down any worsening of disability or symptoms. Drugs used for the treatment of symptoms or relapses are excluded from this category.

We are interested in ALL types/brands of DMTs including licensed, off-label as well as originator and follow-on generics or biosimilars or any DMTs accessed from other countries to treat people with MS in your country. You will find a complete list of DMTs itemised at question B.

If you do not have a source of evidence for these questions, please consult with other health professionals in the country to provide estimates representative of the whole country.

QA. Please **estimate** the **percentage of people diagnosed with MS** in the country, who are **currently being treated** with disease modifying therapies (DMTs).

We recognise that some people are not offered DMTs by their healthcare professional because there is not a DMT suited to their situation, they decide not to take DMTs, that DMTs may not be covered by their healthcare system or insurance or it is unaffordable and we also want you to include the estimated percentage of people who are in this group.

Please round your percentages to whole numbers (no decimal places) and input the number without the % symbol (i.e. enter 20 not 20%). Please ensure that the two figures you enter add to 100.	*Input the estimated percentage in the boxes below.*
i) Percentage of people diagnosed with MS who **are** currently treated with DMTs	
ii) Percentage of people diagnosed with MS who are **not** currently treated with DMTs	
NB the figures for i) and ii) combined should add to 100%	*100%*

If you do not know the percentage of people treated with DMTs leave the question above blank and select the option below

[ ] Percentage of people treated with DMTs unknown

QB. The table listed below shows all the different types of disease modifying therapies (DMTs) that are **used for the treatment** of MS around the world, listed in alphabetical order.

i) In the **first column** of the table below, please indicate which disease modifying therapies (DMTs) are **used for the treatment** of MS in the country.

Please indicate all DMTs used (including off-label, originator, generics, biosimilars and any DMTs accessed from other countries). Please exclude any drugs used just to treat symptoms or relapses.

To help you answer this question, please click on this **link** *and review the data that was provided in 2020. To see your country data, please select your country in the dropdown menu at the top of the table.*

ii) Of the people with MS being treated with DMTs, please indicate in the **second column** in the table below, the estimated percentage taking each type of DMT used in the country

Please ensure you input a number to indicate the % of people treated with each DMT used in the country.

*Please **enter numeric values only**. Please round your percentages to whole numbers (no decimal places) and input the number without the % symbol (i.e. enter 20 not 20% or 3 not 3%). Please enter 0% if less than 0.5% of people are using the treatment. **Please ensure that all the data you enter across the DMTs** adds to 100.*

*If you **cannot provide estimates** on the percentage of people treated with each DMT then **type 100 in the box on row 32 (shaded orange) and leave all the other boxes blank.***

*If you **cannot estimate for all DMTs** (for example you know a percentage of people with MS are treated but you are unsure with what DMT), there is a code at the bottom of the list row 33 (shaded green) to capture the percentage who are treated but the DMT they are treated with is unknown and to ensure your answer adds to 100. (please check your percentages add to 100%)*

	i) **Please tick if the DMT is used at all for the treatment of MS in the country**	ii) **Of the people with MS being treated with DMTs, please indicate the estimated percentage taking each type of DMT used in the country**
1. Alemtuzumab, ATC: L04AA34		
2. Azathioprine, ATC: L04AX01		
3. Cladribine (subcutaneous or IV), ATC: L01BB04		
4. Cladribine (oral), ATC: L04AA40		
5. Cyclophosphamide, ATC: L01AA01		
6. Dimethyl fumarate, ATC: L04AX07		
7. Diroximel fumarate, ATC: L04AX09		
8. Fingolimod, ATC: L04AA27		
9. Fludarabine, ATC: L01BB05		
10. Glatiramer acetate, ATC: L03AX13		
11. Interferon-beta 1a, ATC: L03AB07		
12. Interferon-beta 1b, ATC: L03AB08		
13. IV Immunoglobulin (IVIG), ATC: J06BA02		
14. Leflunomide, ATC: L04AA13		
15. Methotrexate, ATC: L04AX03		
16. Minocycline, ATC: J01AA08		
17. Mitoxantrone, ATC: L01DB07		
18. Monomethyl fumarate, (No ATC code)		
19. Mycophenolate mofetil ATC: L04AA06		
20. Natalizumab, ATC: L04AA23		
21. Ocrelizumab, ATC: L04AA36		
22. Ofatumumab, ATC: L04AA52		
23. Ozanimod, ATC: L04AA38		
24. Peginterferon-beta 1a, ATC: L03AB13		
25. Ponesimod, ATC: L04AA50		
26. Rituximab, ATC: L01XC02		
27. Siponimod, ATC: L04AA42		
28. Teriflunomide, ATC: L04AA31		
29. Other DMT (specify _____)		
30. None – No DMTs used in the county		
31. Not sure what DMTs are used		■■■
32. Can't provide estimates on the % of people treated with each DMT	■■■	(orange)
33. Percentage of people treated with a DMT but the type of DMT used is unknown	■■■	(green)
		Please note the % above should add to 100%

iii) Please tell us more about the **usage and number of people being treated with DMTs** in your country, including any reasons for changes in use since 2019. Examples could be because you have clinical practice guidelines for prescribing DMTs that affect the number treated with each DMT (if so please specify what these are), new DMTs have been licensed/approved for use (please say which ones), change in decisions regarding reimbursement of DMTs (please explain what the reimbursement decisions are) etc.

iv) Please include the types of source(s) you consulted to provide this information regarding **DMTs used to treat people with MS and the percentage being treated in the country.**

If you have estimated this information or it is based on your opinion – please select the "Your personal opinion" code and indicate any assumptions or data you used in the comment box below.

*Please indicate **all** sources used.*

1. Published academic paper or a poster/platform presentation at a scientific conference
2. Patient data (patient register government or health service statistics/electronic medical records, insurance claims data, patient surveys)
3. Advocacy Group Report e.g. from a MS organisation
4. Official Policy report from Government/Hospital
5. Opinion of medical professional
6. Opinion of MS Society/patient organization
7. Your personal opinion (specify how you have estimated this:_____)
8. Other type of data source (specify_____)

Please also note anything specific about the data source and the types of people with MS that the source is based on that is important for us to be able to interpret the data. For example, is it representative of all people with MS in the country or just people being treated at a certain hospital? Does it exclude certain groups such as those with disabilities?

Please specify any assumptions or data you have considered when providing opinions or estimates. Please also provide further details or links to any public academic papers or patient data that you have consulted or any further information about the source that is relevant.

QC. Please estimate the percentage (%) of people with MS in the country that can **afford each of the listed DMTs**, considering factors such as how many people have some form of health insurance, the levels of reimbursement for the treatments and/or any associated out-of-pocket costs.

Please provide an answer for each of the DMTs listed.

*Please type **N/A** if the DMT is **not available in your country** <u>or if you are unable to prescribe it for MS.</u>*

Please give a percentage between 0% and 100% and round to whole numbers (no decimal places) for <u>each</u> DMT available to prescribe for MS in the country (even if it is not used).

Please allocate a percentage of between 0% = no one or less than 0.5% can afford this DMT, whilst 100% = everyone can afford this DMT (including if it is free for people with MS)

If you have more than one brand, please provide the affordability estimate for the cheapest brand available.

If you cannot provide an answer for this question, please indicate this below by selecting "not sure" at the bottom

DMT type *(includes off-label, originator, generics, biosimilars and any DMTs accessed from other countries)*	Please indicate the estimated % of people in the country where each DMT would be <u>affordable</u>
1. Alemtuzumab, ATC: L04AA34	
2. Azathioprine, ATC: L04AX01	
3. Cladribine (subcutaneous or IV), ATC: L01BB04	
4. Cladribine (oral), ATC: L04AA40	
5. Cyclophosphamide, ATC: L01AA01	
6. Dimethyl fumarate, ATC: L04AX07	
7. Diroximel fumarate, ATC: L04AX09	
8. Fingolimod, ATC: L04AA27	
9. Fludarabine, ATC: L01BB05	
10. Glatiramer acetate, ATC: L03AX13	
11. Interferon-beta 1a, ATC: L03AB07	
12. Interferon-beta 1b, ATC: L03AB08	
13. IV Immunoglobulin (IVIG), ATC: J06BA02	
14. Leflunomide, ATC: L04AA13	
15. Methotrexate, ATC: L04AX03	
16. Minocycline, ATC: J01AA08	
17. Mitoxantrone, ATC: L01DB07	
18. Monomethyl fumarate, (No ATC code)	
19. Mycophenolate mofetil ATC: L04AA06	
20. Natalizumab, ATC: L04AA23	
21. Ocrelizumab, ATC: L04AA36	
22. Ofatumumab, ATC: L04AA52	
23. Ozanimod, ATC: L04AA38	
24. Peginterferon-beta 1a, ATC: L03AB13	
25. Ponesimod, ATC: L04AA50	
26. Rituximab, ATC: L01XC02	
27. Siponimod, ATC: L04AA42	
28. Teriflunomide, ATC: L04AA31	
29. Other DMT (specify _____)	

If you cannot provide estimates about the affordability of each DMT in the country please indicate below

☐ Not sure - Can't provide estimates about the affordability of each DMT in the country

i) Please tell us more about the **affordability of DMTs for people with MS** in your country, to help provide context. For example, the percentage of the population covered by health insurance, whether this health insurance covers all DMTs used in the country and if not which ones and why, which DMTs are reimbursed and any other out-of-pocket costs that affect affordability.

ii) Please include the types of source(s) you consulted to provide this information regarding the **affordability of DMTs for people with MS in the country.**

If you have estimated this information or it is based on your opinion – please select the "Your personal opinion" code and indicate any assumptions or data you used in the comment box below.

Please indicate all sources used.

☐	1. Published academic paper or a poster/platform presentation at a scientific conference
☐	2. Patient data (patient register government or health service statistics/electronic medical records, insurance claims data, patient surveys)
☐	3. Advocacy Group Report e.g. from a MS organisation
☐	4. Official Policy report from Government/Hospital
☐	5. Opinion of medical professional
☐	6. Opinion of MS Society/patient organization
☐	7. Your personal opinion (specify how you have estimated this:_____)
☐	8. Other type of data source (specify_____)

Please also note anything specific about the data source and the types of people with MS that the source is based on that is important for us to be able to interpret the data (is it representative of all people with MS in the country or just people being treated at a certain hospital? Does it exclude certain groups such as those with disabilities?)

Please specify any assumptions or data you have considered when providing opinions or estimates. Please also provide further details or links to any public academic papers or patient data that you have consulted or any further information about the source that is relevant.

The Expanded Disability Status Scale (EDSS)
The next questions are about the Expanded Disability Status Scale (EDSS). The Expanded Disability Status Scale was developed by a neurologist called John Kurtzke and is a way of measuring how much someone is affected by their MS. The scale ranges from 0 to 10 in 0.5 in 0.5 unit increments that represent higher levels of disability. Scoring is based on an examination by a neurologist. QD. Please indicate below, the estimated percentage of people with MS in the country which fall into each of the Expanded Disability Status Scale (EDSS) groupings below.

QD. Please indicate below, the estimated percentage of people with MS in the country which fall into each of the Expanded Disability Status Scale (EDSS) groupings below.
If you cannot estimate the number of people who fall into each group, please type in 100% in the last row "% of people with MS where the EDSS score is unknown"

Expanded Disability Status Scale (EDSS) category groupings	% of people with MS in each EDSS category
% of people with MS with **no disability (EDSS level 0)**	
% of people with MS with **mild disability (EDSS levels 1–3)**	
% of people with MS with **moderate disability (EDSS levels 3.5–5.5)**	
% of people with MS with **severe disability (EDSS levels 6-7.5)**	
% of people with MS with **very severe disability (EDSS levels 8 or higher)**	
% of people with MS where the **EDSS score is unknown**	
	Please note the % above should add to 100%

i) Please select the option that best describes the composition of the EDSS data you have provided

☐ 1. EDSS data based on **all** people with MS in the country
☐ 2. EDSS data based on **a representative sub-sample** of people with MS in the country
☐ 3. EDSS data based **only on those people with MS who are treated with DMTs or being monitored**
☐ 4. EDSS data based only on **another sub-group of people with MS that is not-representative** of the people with MS population - for example only includes people of a certain age (specify_____)

ii) Please use this space to provide more detail and context regarding your answers on the **proportion of people in each EDSS category** or anything that is useful to help us interpret the data or representativeness of the data (or reasons why you are unable to provide data)

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iii) Please include the types of source(s) you consulted to provide this information regarding **the proportion of people with MS in each EDSS disability grouping.**

If you have estimated this information or it is based on your opinion – please select the "Your personal opinion" code and indicate any assumptions or data you used in the comment box below.

*Please indicate **all** sources used.*

☐ 1. Published academic paper or a poster/platform presentation at a scientific conference
☐ 2. Patient data (patient register government or health service statistics/electronic medical records, insurance claims data, patient surveys)
☐ 3. Advocacy Group Report e.g. from a MS organisation
☐ 4. Official Policy report from Government/Hospital
☐ 5. Opinion of medical professional
☐ 6. Opinion of MS Society/patient organization
☐ 7. Your personal opinion (specify how you have estimated this:_____)
☐ 8. Other type of data source (specify_____)

Please specify any assumptions or data you have considered when providing opinions or estimates. Please also provide further details or links to any public academic papers or patient data that you have consulted or any further information about the source that is relevant.

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Collaborators and Acknowledgments
QE Please indicate whom was consulted or collaborated with in (including yourself) order to provide the answers to these questions to ensure a comprehensive picture of the clinical management of MS in the country. *Please indicate all that apply*

☐ 1. Clinicians based in the country or with experience of working in the country
☐ 2. Other experts in the country
☐ 3. Didn't consult anyone else – no other experts with knowledge of DMTs or EDSS in the country
☐ 4. Didn't consult anyone else – you lacked time to consult any other clinicians or experts in the country
☐ 5. Didn't consult anyone else – you tried to approach other experts but they lacked time to take part
☐ 6. Other (please specify)_____

QF Would you like your name to appear in the list of contributors to the Atlas of MS update?

We will not make public any personal information without your permission, and the information displayed will be limited to your name and country.

☐	1. Yes *(Please specify below)*
☐	2. No *(Please skip to QG)*

Please specify how you would like your name to appear in the list of contributors, including any titles. *see website for examples https://www.atlasofms.org/collaborators-and-acknowledgements).*

QG. Is there anyone else who you have collaborated with to complete this survey who would like to appear in the list of named contributors to the Atlas of MS update and have agreed for their name to be passed to MSIF?

Please ensure that you have consent to provide us with their name and for us to publish this in our report (the information displayed will be limited to their name and country).

☐	1. Yes *(Please specify details below)*
☐	2. No *(Please skip to the thank you)*

Please specify the contact name (including any titles) and email address for each collaborator below.

Please ensure that you have consent to provide us with their name and for us to publish this in our report (the information displayed will be limited to their name and country)– see the website for examples - https://www.atlasofms.org/collaborators-and-acknowledgements*).*

	Name Format of name should be: **Title (Dr. Prof. Ass. Prof), Forename, Surname:** E.g.: Ass Prof. Diana King	Email address *(this is so we can reach out for clarifications/queries as well as updates about the Atlas)*	Role **Please select ONE option that best describes their role. They are…** 1. **Clinician/other health professional/Researcher** 2. **Employee or volunteer for an MS society** 3. **Person with or affected by MS** 4. **Another role**
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

Thank You

Thank you very much for completing this survey – we are very grateful for your help.

You can find out more about MSIF's work and how you can join in by:

- Signing up to our newsletters: https://www.msif.org/get-involved/our-newsletters/

- Visiting the Atlas of MS website: www.atlasofms.org

- Exploring our work to improve access to treatments and healthcare (and how the Atlas data supports this work): https://www.msif.org/improving-access-to-ms-treatment-and-healthcare/

- Reviewing the grants available for clinicians/researchers working in low or middle income countries: https://www.msif.org/research/awards-grants-and-fellowships/

- Exploring the World MS Day website https://worldmsday.org/about/. This important date for the MS calendar is officially marked on **30 May** and brings the whole global MS community together to share stories, raise awareness and campaign. Make a difference and encourage everyone you know to join-in!