I. Notes on use/Disclaimer

The EuroGuiDerm guideline on the systemic treatment of psoriasis vulgaris was developed in accordance with the EuroGuiDerm Methods Manual v1.3, which can be found on the website of the European Dermatology Forum (EDF), subsection EuroGuiDerm/EDF Guidelines https://www.guidelines.edf.one/guideline-methods

These evidence- and consensus-based guidelines contain recommendations that were developed to assist clinicians in the care of patients in specific clinical conditions. The recommendations are based on the available evidence and their development followed a pre-specified, standardized process. Nevertheless, guidelines do not replace the clinicians' knowledge and skills, since guidelines never encompass therapy specifications for all medical decision-making situations. Guidelines should not be deemed inclusive of all proper methods of care nor exclusive of other methods of care reasonably directed to obtaining the same results. Deviation from the recommendations may be justified or inevitable in specific situations. The ultimate judgment regarding patient care must be individualized and must be made by the physician and patient in the light of all presenting circumstances.

Safety aspects that were considered within these guidelines do not represent a comprehensive assessment of all available safety information for the included interventions. They are limited to those aspects chosen for evaluation and the information available in the included clinical trials. Readers must carefully check the information in these guidelines and determine whether the recommendations (e.g. regarding dose, dosing regimens, contraindications, or drug interactions) are complete, correct, up-to-date and appropriate.

European guidelines are intended to be adapted to national or regional circumstances (regulatory approval and availability of treatments, health care provider and insurance systems). Particularly, the approval situation/availability/reimbursement of the different treatment options has to be adapted to the national situation. Thus, the national medical societies associated adopting European Guidelines will be responsible for the adoption and implementation of the guidelines on a national level.

II. Accompanying documents:

The EuroGuiDerm Guideline on the systemic treatment of Psoriasis vulgaris – Methods & Evidence report is available as supplementary file. All other documents, such as the IFPA patient guide, are available alongside the guideline document on the EDF website: https://www.guidelines.edf.one/guideline-methods

III. Funding

The development of this EuroGuiDerm guideline was funded through the EuroGuiDerm Centre for Guideline Development. The European Dermatology Forum (EDF) is responsible for fundraising and holds all raised funds in one account. The EuroGuiDerm Team is not involved in fundraising or in the decision making on which GL/CS development is funded. The decisions on which GL/CS is funded are made by the EuroGuiDerm Board of Directors independently. The EDF or any other body supporting guideline work is never involved in the development of this guideline and had no say on its content or focus.

IV. Scope and purpose of this guideline

The overall aim of this guideline is to provide guidance for optimal treatment selection and management in the treatment of adults with moderate to severe plaque type psoriasis. Optimal treatment selection and management are meant to reduce morbidity caused by psoriasis and to improve the health related quality of life of affected individuals.

The objectives of the guideline are to:

- Include new treatments and the evidence that has become available
- Update the recommendations regarding systemic treatment options
- Develop a treatment algorithm including systemic treatment options
- Provide clear recommendations on how to best monitor and manage patients considering the available treatment options
- Develop several short guidance documents with visual tools for ease of implementation
- Provide guidance on the treatment of special populations and difficult clinical situations (mostly expert consensus)

V. Population and health questions covered by the guideline

The target population are patients with plaque type psoriasis of moderate to severe severity, and patients with psoriatic arthritis, who have also been diagnosed with moderate to severe psoriasis vulgaris.

Leading health questions - all referring to adult individuals (regardless of sex or gender) with moderate or severe plaque type psoriasis – are:

- Which treatment option should be chosen with regard to patients' needs, taking efficacy, safety/tolerability of the different treatment options and comorbidities into consideration?
- How should the selected treatment option best be managed and monitored?
- How should frequent comorbid situations (e.g. concomitant arthritis) best be managed?

Necessary inclusion criteria for treatments was a European license for the treatment of psoriasis of the skin. Whenever possible and feasible, the recommendations are evidence-based, taking the results of systematic evidence synthesis based on rigorous methods [1] as well as on the practical experience obtained by the expert group, into account.

This guideline covers the use of 'conventional' treatments (acitretin, ciclosporin, fumarates, methotrexate), biologic therapies targeting TNF (adalimumab, etanercept, certolizumab pegol, infliximab), IL-12/23p40 (ustekinumab), IL-17A (ixekizumab, secukinumab), IL-17A/IL-17F (bimekizumab), IL-17RA (brodalumab), IL-23p19 (guselkumab, risankizumab, tildrakizumab),the group of 'small molecules' (apremilast) and tyrosinekinase inhibitors (deucravacitinib).

Relevant comparison are head-to-head studies of the above mention interventions or versus placebo. The outcomes chosen are: 90% improvement in the Psoriasis Area Severity Index (PASI 90) and severe adverse events (SAEs), and PASI 75 and adverse events (AEs).

Additionally, the below listed comorbidities and special situations are addressed by the guideline.

Table 1: Overview of topics & key question in relation to comorbidities and special patient populations/issues

TOPIC	QUESTION(S)
Psoriatic arthritis	– **How should psoriasis patients with concomitant psoriatic arthritis be managed?**
Inflammatory bowel disease	– **How should psoriasis patients with inflammatory bowel disease be managed?**

Cancer	– **How should psoriasis patients with a history of malignancies be managed?**
Depression	– **How should psoriasis patients with a history of depression and/or suicidal ideation be managed?**
Diabetes mellitus	– **How should psoriasis patients with diabetes mellitus be managed?**
Heart disease	– **How should psoriasis patients with ischaemic heart disease and/or congestive heart failure be managed?**
Kidney disease	– **How should psoriasis patients with kidney failure / renal impairment be managed?**
Neurology	– **Which treatments are appropriate for psoriasis patients with neurological diseases?**
Hepatitis	– **When and how should psoriasis patients be screened for viral hepatitis and how should patients who test positive be managed?**
Tuberculosis screening	– **How to screen for tuberculosis before and during biologic treatment?**
Tuberculosis and treatment	– **How to manage psoriasis in patients with positive tuberculosis test results?**
Pregnancy	– **How should psoriasis patients with a wish for pregnancy in the near future or who are pregnant be managed?**
Vaccinations	– **How should vaccinations in psoriasis patients on systemic treatment be managed?**
Immunogenicity	– **What is the role of anti-drug antibodies in biologic treatments?**

VI. Targeted users of this guideline

This guideline applies to Europe and both, hospital and practice (private and public) based dermatologists are the target users. In addition, national medical societies are invited to adopt this guideline or adapt them to their local contexts. It is also meant to guide payers and health care authorities.

A Patient Guide to using The EuroGuiDerm Guideline for the Systemic Treatment of Psoriasis Vulgaris

by the IFPA

This guideline applies to:

- People living with moderate to severe psoriasis vulgaris
- The caregivers, family and friends who support them
- Psoriasis patient experts and advocates
- Healthcare providers

To best use the guideline, it is also recommended that health care practitioners be given sufficient time to discuss their proposed treatment approach with patients during consultations. [2] More Information can be found in the IFPA patient guide under: EuroGuiDerm Guideline IFPA.

This **joint Q&A** section provides an overview of topics and key questions you may have. Remember that these responses may not be exhaustive! We strongly recommend working closely with your care provider to select the best treatment for you.

1. What information is contained in this guideline?

   The guide contains information about different kinds of treatment including conventional systemic treatment, biologic therapies, biosimilars and other new treatment options often grouped under the name of "small molecules". It also offers guidance for specific comorbidities and clinical situations such as pregnancy and vaccinations.

2. Can I talk to my healthcare provider about information in the guideline?

   We hope that you will! Whether you are visiting a dermatologist, primary care provider, or other specialist, we encourage you to build an informed patient-provider relationship using the EuroGuiDerm guidelines website as a reference. Propose an in-depth conversation during consultation and care visits. Your doctor is interested in your concerns and overall health improvement.

   PD Dr. med. Julia-Tatjana Maul, and consultant in the Department of Dermatology at the University Hospital Zurich *recommends that patients inform themselves using the European Psoriasis Guideline or other resources such as patient leaflets about Biologics and Psoriasis Treatment from the EADV [3]. These are written more from a patient's perspective and are less scientific.*

3. What about newer treatment options? When can I start on those therapies?

   Biologics are protein-based drugs which target specific immune mediators and are approved for the treatment of Pso/PsA (psoriatic disease). Other newer treatment options block enzymes inside cells, e.g. phosphodiesterase 4 or tyrosine kinase 2. With the introduction of biologic medications and other recently approved treatments, we now have more options, and there has been proven improvement in quality of life of patients [4].

   The best care may vary among individual patients. Discuss your treatment options with your dermatologist and find out what the best-recommended care looks like for you.

4. What about biosimilars and newer treatments?

   Biosimilars are mimic products that can be generated after licensed biologic also called an ´originator´ loses its patent protection. As the generation of biosimilars lacks the enormous development costs, they are often more affordable than their originator. To obtain the approval for all indications of the originator, biosimilars have to perform clinical phase 3 trials in the first licensed indication of the originator only.

   In its position paper on biosimilars, the International Federation of Psoriasis Associations (IFPA) welcomes the introduction of safe and effective biosimilars that can improve access to treatment options [5]. However, as always, IFPA emphasizes the importance of the patient-provider relationship in making individual decisions to switch from an originator to a biosimilar.

5. Which Health Care Provider should I talk to about comorbidities?

   All healthcare professionals involved in your care, including your dermatologist, should be aware of psoriasis and its comorbidities [6]. The guideline has information on the management of psoriasis-associated conditions such as: psoriatic arthritis, mental health conditions, inflammatory bowel disease, diabetes and heart diseases.

   Inform your treatment team about any other health conditions you experience. They will assist in timely screening, diagnosis and referrals to the appropriate specialists.

6. If I am pregnant, breastfeeding, or I desire to become pregnant: what are my treatment options?

   Like many other chronic illnesses, special consideration is taken in your treatment plan when you plan to get pregnant, during pregnancy, and while breastfeeding [7]. Besides talking to your dermatologist, it may help to talk to your gynecologist as well.

7. What does the guideline recommend about vaccinations while on treatment for Psoriasis?

Before you get your annual or seasonal vaccinations always talk to your dermatologist.

Here is what Julia-Tatjana Maul, MD, *recommends the following based on evidence on vaccines and treatment of patients with psoriasis vulgaris.*

´Psoriasis on its own should not be considered a reason to deviate from standard vaccination recommendations. In psoriasis patients, vaccination using dead vaccines and live vaccines can be performed at any time, unless a systemic treatment is given that necessitates a different strategy. However, before initiating a systemic treatment, vaccination status should be checked and completed. The seasonal flu vaccination is particularly recommended and national recommendations for vaccination should be followed. The use of life vaccines when being treated with a systemic anti-psoriatic treatment needs to be discussed with your doctor at the time point of vaccination and duration of treatment´.

8. What should I know about use of psoriasis medication if I have another bacterial/viral infection or during pandemic outbreaks?

PD Dr. Maul suggests contacting your doctor when having a bacterial or viral infection and discuss with your doctor on an individual basis if your anti- psoriatic treatments need to be stopped or paused.

9. Are my perspectives on treatment relevant? What about patient experience?

Yes! It is important that your experience as a patient and your perspectives on treatment be taken into consideration. In fact, your perspective is so important that two measures have been developed to record your perspective during clinical consultations: Patient Reported Outcome Measure (PROMs) and Patient Reported Experience Measures (PREMs).

PROMs offer a valid and reliable description of your health status from your own perspective and PREMs report your satisfaction with treatment while complementing guidelines beyond clinical care [8].

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