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Expert consensus document on criteria for assessing disability and invalidity in chronic primary headache

From the law to the implementation of diagnostic-therapeutic pathways

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Editors: *Cristina Tassorelli, Giorgio Sandrini, Cherubino Di Lorenzo, Rosa Maria Gaudio, Lara Merighi, Elena Ruiz de la Torre*

In memory of Paolo Rossi

Under the patronage of:

Alleanza Cefalalgici-Fondazione CIRNA Onlus
and
European Migraine & Headache Alliance

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Preface

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Following the Italian parliament's recent promulgation of Law no. 81/2020, concerning the recognition of chronic primary headache as a social disease, Alleanza Cefalalgici-Fondazione CIRNA Onlus, in agreement with the European Headache & Migraine Alliance (EMHA), promoted the creation of a Committee of experts with the aim of producing a consensus document on the said law.

We considered it worthwhile publishing, in this supplement, the document that was duly drafted with the help of representatives of patient associations, scientific societies, and institutions, many of whom had already played a key role in getting this important law approved — a protracted and complex process that was also emblematic of the way in which constructive cooperation can be achieved between patients and the various bodies and institutions that take care of their problems and interests.

It should be emphasized that the passing of this law, although very important, is only the starting point for a still long and complex journey that will involve the approval of the implementing decrees and then their application at regional level. The latter step will require coordination with the Italian regions, given that some of them, such as Lombardy, had already deliberated on this issue.

The virtuous path followed thus far in Italy has aroused interest among other Headache Patient Associations represented, at European level, by EMHA, who have asked Alleanza Cefalalgici to disseminate information aimed at promoting similar initiatives in their own countries.

Alleanza Cefalalgici-Fondazione CIRNA Onlus, as mentioned above, promoted the establishment of a Committee made up of experts and representatives of scientific societies and other bodies involved in the preparatory phase of this law. The resulting consensus document aims to clarify how Law no. 81/2020, as approved by the Italian parliament, should be interpreted and implemented, and, therefore, to provide indications on the problems that must be addressed by the implementing decrees. It will also make it easier both to evaluate the conditions needing to be fulfilled in order for a chronic primary headache to be deemed to produce a situation of disability, and to define useful criteria for its quantification.

A meeting concerning the social problems associated with headaches, chronic headaches in particular, was held in Rome last year. The meeting was organized by EMHA in close collaboration with Alleanza Cefalalgici-Fondazione CIRNA Onlus, which was a co-founder and remains an active member of EMHA. The meeting was the first in a series that will take place in various European countries as part of an awareness campaign promoted by EMHA. In keeping with the efforts of EMHA, we decided it would be helpful to include documents useful for extending the Italian experience to other European countries. Accordingly,

this supplement includes the texts of Law no. 81/2020 and of a Lombardy regional law concerning a proposal for evaluating the disability produced by severe headache and its impact on patients' quality of life. Also included are parts of an agreement between the Italian state and Italian regions, approved in February 2023, concerning the implementation of diagnostic-therapeutic pathways for chronic headache.

Finally, we would like to thank Lundbeck whose unconditional support has made it possible to publish this supplement.

Consensus recommendations on the criteria for assessing disability and invalidity in chronic primary headache °

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European Migraine and Headache Alliance

°This paper is an English translation of the same paper published in *Conf. Cephalal. et Neurol. 2022; Vol. 32, N. 1* . The document has been updated in parts concerning new, recently approved laws.

Glossary

INPS: Italian National Social Security Institute
INAIL: National Institute for Insurance against Accidents at Work
CMO: Hospital Medical Commission
ANMIC: Associazione Nazionale Mutilati Invalidi Civili

Context and purpose

Headaches are highly prevalent and disabling conditions. Around half of the world's population is estimated to have experienced recurrent headache in the course of the past year, while 3% suffers from chronic headache, i.e., headache present on at least 15 days per month (1). According to the "Global Burden of Disease 2019" study, headache, in its various forms, is the second leading cause of "life lived with disabilities" in the age group 10-24 years, and the fifth in people aged 25-49 years (2). Headaches are coded and described on the basis of strict clinical diagnostic criteria, systematically presented in an international classification, now in its third edition: the International Classification of Headaches, third edition (ICHD-3) (3). In particular, the classification distinguishes the primary forms (those in which the headache itself is the disease) from the secondary ones (in which the headache is a symptom of another disease). The primary headaches are

covered in the first four chapters of ICHD-3, and they are: 1) migraine; 2) tension-type headache; 3) trigeminal autonomic cephalalgias (TACs) (including cluster headache); and 4) other primary headache disorders (Chapters 1-4, respectively) (3).

The Italian parliament recently passed a law (no. 81 of 14 July 2020) stating that primary headache present for at least one year, as ascertained on the basis of a diagnosis made by a specialist at an accredited center for the diagnosis and treatment of headaches, which certifies its disabling effect, constitutes a social disease. In detail, the legislator identified the following forms: a) chronic and high-frequency migraine; b) chronic daily headache with or without overuse of analgesic drugs; c) chronic cluster headache; d) chronic paroxysmal hemicrania; e) short-lasting unilateral neuralgiform headache attacks with conjunctival injection and tearing; f) continuous migraine (4).

The decrees necessary to implement law no. 81/2020 have recently been approved. However, the law does not expressly include primary headache treatments among the "Essential Levels of Assistance" (LEA), does not provide for specific protections for affected individuals, and fails to indicate how headache-related disability should be quantified.

Therefore, there are still aspects that need to be better clarified and specified, as well as health protection needs and medicolegal requirements relating to social welfare protection that need to be better defined.

This consensus document is aimed, in particular, at doctors involved in the management of patients with headache, i.e., general practitioners, community neurologists, and headache center specialists. In addition, the document may also be of interest to coroners and to those, in institutional settings, required to assess the disability produced by chronic headache and any comorbidities. Its main aims are to precisely define the framework of application of law no. 81/2020, and to provide a practical guide, so as to create, among doctors, a shared awareness of the opportunities offered to patients by the current rules, an operating method that allows patients enjoy the benefits of the law, and finally, a common language making it possible to better inform the health authorities of the specific characteristics of each case.

It should be noted that, prior to law no. 81/2020, some Italian regions, e.g., Lombardy, had, within the sphere of their competences, already partially regulated this sector, proposing innovative measures concerning headache patients. Some of these regulations are reported in a recent supplement of *Confinia Cephalalgica et Neurologica*, which also collects a series of contributions on the topic discussed in this consensus document (5).

Methodology

The establishment of the Committee that developed this consensus document was promoted by the non-profit foundation CIRNA under the patronage of Alleanza Cefalalgici-Fondazione CIRNA Onlus (Al. Ce.-CIRNA) and the European Migraine and Headache Alliance (EMHA). The Committee is made up of specific stakeholders and experts in the field, many of whom work in national and international scientific societies active within it.

Representatives of the patients' association Alleanza Cefalalgici, although not directly involved in the consensus-reaching process, helped to formulate the questions to be answered by the experts, and also had the opportunity to offer suggestions and comments in the intermediate stages of the work, as well as review and approve the final version of the document. Preliminarily, a virtual meeting was held between the various members of the Committee to agree on the need for a declaration of consensus, on the composition of the Steering Committee, and on the mission and purposes of the document. Subsequently, the work was continued via email and through periodic virtual meetings.

From the specific questions initially proposed, the Committee members selected and developed those to be included. Any that were similar or complementary were combined and refined, since the aim was to explore all the relevant areas of interest through the smallest possible number of questions. For each question, a space was provided for open answers, as well as multiple choice answers on which to reflect. The Committee members were then required to answer the questions. They were not allowed to discuss their answers until the next meeting, and could skip any of the

more technical questions they may not be qualified to answer. After each round of questions and responses, a facilitator prepared a summary document which was then discussed and refined during a subsequent online meeting attended by all the members of the Committee, including the lay ones. Then, the questions were again put to the members, who were encouraged to review their responses in the light of the discussion, so as to arrive at clear and shared answers. In total, three question and answer rounds were carried out to reach consensus on all the different aspects discussed.

The Steering Committee was appointed to coordinate the work and draw up the preliminary documents. This work was conducted along the lines of other consensus conferences (6), starting from the existing scientific literature in order to produce an EBM document and remain within the confines of the existing regulatory framework. Given the eminently applicative purpose of the document, the bibliography has been confined to a short list of references.

The answers listed below, formulated taking into account the relevant regulatory and scientific context, are intended mainly to provide recommendations or clarification on how the criteria for applying law no. 81/2020 should work in practice.

Evidence, questions and recommendations

Q1 - *What are the forms of chronic headache covered by Law no. 81 of 14 July 2020 containing "Provisions for the recognition of chronic primary headache as a social disease" (Italian Official Gazette, no. 188 of 28 July 2020, entry into force 12-8-2020)?*

A1 – The law recognizes, as *chronic headache*, clinical forms that do not have a primary etiology or pathogenesis attributable another clinical or pathological situation (i.e., that are not secondary to other nosologically defined conditions, e.g., neoplasms, traumas, etc.), and that in terms of the quantity of clinical manifestations, can objectively be said to occur on at least 15 days a month. These forms are *in extenso*: chronic and high-frequency migraine; chronic daily headache with or without overuse of analgesic drugs; chronic cluster headache; chronic paroxysmal hemicrania; short-lasting unilateral neuralgiform headache attacks with conjunctival injection and tearing (SUNCT); continuous migraine. Furthermore, albeit not specifically provided for by the law, forms of headache with symptoms cumulatively affecting patients on at least 15 days per month for over a year, leading to significant disability, such as new daily persistent headache, should also be considered to qualify for this recognition (7).

Q2 - *What are the requirements?*

A2 - In Italy, chronic primary headache, of any form, is recognized as a social disease (see Italian Ministerial Decree of 12 June 1972 and subsequent amendments) if it has been diagnosed for at least one year by a headache specialist at an accredited center for the diagnosis and treatment of headaches, who certifies its existence, duration, and intensity. The legislator provides no clear definition of the term "accredited center", but it is believed to refer to public and private centers accredited by the national health system to carry out headache examinations, and therefore not solely to public centers identified by the Italian regions within their respective territories and currently authorized to prescribe special therapies, including new drugs, such as monoclonal antibodies.

Q3 - *How should the diagnosis be confirmed?*

A3 - For all the forms of chronic primary headache listed, the diagnosis is exclusively clinical and not instrumental. Thus, it is based on the patient's history, confirmed by a clinical neurological examination found to be negative for any specific pathology that might justify the clinical picture, and, finally, supported by 12 months of monitoring and observation at the headache center in question. Specific tests are carried out only in the presence of so-called sentinel symptoms, in order to rule out secondary headache, in accordance with the main national and international guidelines on the subject. The form must be indicated in the diagnosis using clear common terminology that is consistent with the approved international nosography, and there must be no "subjective interpretations". The diagnosis must comply with the criteria of the International Headache Society (IHS) (3), which include criteria for the exclusion of secondary forms.

Q4 - *Is headache monitoring with diary cards necessary?*

A4 - a) Headache centers always require patients to keep a headache diary (paper, electronic, app), which is a fundamentally important instrument in this setting in order to confirm the diagnosis and the presence of the headache on at least 15 days per month to confirm chronic forms (8). In addition to diaries, the specialist should administer the patient specific tests in order to document the impact of the clinical form on the patient's daily life. The importance of the diary lies in the fact that it allows correct appreciation and therefore certification of the patient's current and overall situation, exactly as is required for any other pathological condition; this is crucial for determining and understanding incident aspects related to time, place and the specific patient's daily space.

b) In addition to the diary card, it is advisable, in headache patients, to use validated and shared evaluation scales that are aimed at quantifying pain and disability (6,8), and also to consider the patient's socio-family context (9) (see also Q10 and A10). These scales should be administered according to a follow-up plan, so as to document the persistence of pain and disability over time.

Q5 - *Are instrumental checks or diagnostic tests necessary?*

A5 - As already mentioned (see A3), specific tests are carried out only in the presence of so-called sentinel symptoms, in order to rule out a secondary nature of the headache (3,10). According to clinical-anamnestic data on any comorbidities, a patient may need to undergo specific tests in order to better define and stage the same (see Q8 and A8).

Q6 - *Who issues the certification?*

A6 - The specialist at the accredited center who makes the diagnosis and manages the case over the following 12 months. The certification issued by the center constitutes the attestation necessary for any subsequent request for an assessment in order to be able to receive health and welfare insurance benefits.

Q7 - *What comorbidities should be considered?*

A7- The law does not, and cannot, specify this; however, in accordance with good clinical practice, specific internal medical/metabolic, neurological, inflammatory, intestinal, and psychiatric comorbidities must always be investigated, as well as the presence of sleep disorders and disorders of the cervico-mandibular complex, and other types of cranial and orofacial pain. Comorbidities can help to define the overall picture of clinical impairment and must also be framed according to international diagnostic criteria, e.g., according to DSM-5 in the case of mental health disorders (11) (see also Q8 and A8). Consideration should also be given to their possible etiopathological link with the headache, of which they can be an aggravating factor.

Q8 - *How should comorbidities be investigated?*

A8 - The specific investigations conducted differ from patient to patient, and should be prescribed according to correct clinical practice in the light of the history and clinical examination. Furthermore, precise classification of the case may require input from other professionals, such as psychiatrists, psychologists, physiatrists, dentists/gnathologists, maxillofacial surgeons, anesthetists, endocrinologists, and cardiologists. Neurologists, internists and clinical pharmacologists are the ones most commonly involved in second- and third-level diagnostics in headache centers.

Given the high comorbidity of migraine with depressive disorders and anxiety disorders (10.3389 / fnhum.2021.60574), it is advisable, for these disorders, to use simple, rapid and reliable self-administered screening tools based on the DSM-5 diagnostic criteria, such as the *Patient Health Questionnaire-9* (PHQ-9) and the *Generalized Anxiety Disorder 7-item* (GAD-7) scale, respectively.

Q9 - *Should drug resistance and limitations associated with contraindications and treatment side effects be considered?*

A9 - Previously prescribed and administered therapies must always be taken into consideration. Compatibly with their clinical condition, a patient must have exhausted all the main therapeutic options for their headache indicated by literature evidence and reference guidelines, and in the case of medication overuse must have made at least one attempt to withdraw the overused drug. A patient who does not comply with a prescribed treatment due to poor adherence must be distinguished from one whose non-compli-

ance is due to poor tolerance of the treatment. Finally, a patient who, despite taking the prescribed treatments correctly, fails to respond in terms of reduction of monthly headache days and elimination of pain by symptomatic therapy, is to be considered drug resistant, and therefore in greater need of social support. Contraindications to the use of effective drugs due to the presence of comorbidities, particularly cardiological, neurological-internal, and psychiatric, should be considered. Due consideration will be given to newly marketed drugs with high efficacy, specifically indicated for the abovementioned diseases.

The concept of "refractory" or "intractable" headache (12) remains controversial and should be considered in the individual case only after trying all the guideline-recommended treatments except those for which the patient has contraindications or tolerability issues. In the case of headaches associated with overuse of symptomatic drugs, it is necessary to verify that the patient has made at least one correct attempt at drug withdrawal, and also to establish the role of any mechanisms of abuse/dependence (13). This is done also with the aim of ruling out possible reversibility of the clinical condition. *Responders* to drug withdrawal must in any case be evaluated prospectively, given the high frequency of relapses and the reduced response often observed in patients with inveterate forms.

Q10 - *Should the patient's age be considered, and whether or not they work?*

A10 – When a patient struggles to perform, or is unable to perform, their work and/or *routine* everyday activities, this aspect must be given maximum consideration both in the descriptive diary phase, being necessary for the possible subsequent certification phase, and in the administrative assessment phase related to the provision of social welfare benefits. Without wishing underestimate the disability of those affected by a chronic primary headache in old age or when "physiologically" inactive, it is pointed out that particular attention must be devoted to young patients and workers, who need specific protections at school or in the workplace. It should be noted that the work done by housewives equates with normal working activity (Constitutional Court, judgment no.28 / 1995), and also that the various administrative assessment procedures related to the provision of social welfare protections do not change for this category; patients must be made aware of this.

It is important to underline that disability produced by headache should be considered according to the indications provided in the *International Classification of Functional Disability and Health* (ICF) (9), which adopts a bio-psychosocial approach and therefore takes into account the socio-family and psychosocial context, as well as the impact on the patient's daily life activities and living conditions. The role of comorbidities that can significantly impact working activities must be considered (14) (see Q7 and A7). Furthermore, it must be remembered that the different forms of headache covered by law no. 81/2020 are more frequent in women, and must therefore be considered from a gender perspective (15).

Q11 - *What procedures must be followed to obtain a disability assessment?*

A11- It should be remembered that recognition of the "social" nature of the disease does not imply that invalidity or disability related to chronic primary headache is automatically recognized in the individual patient, especially with regard to its quantification. In other words, while recognition of "headache" as a social disease modifies and improves sensitivity to the clinical problem, and consequently invites and demands greater awareness of the medicolegal implications, so as to allow more precise definition of the rights deriving from the protection laws (pensionable invalidity, civil invalidity, "handicap", contribution to healthcare costs, etc.), as well as application of the Essential Levels of Assistance (LEA) (to those who have suffered from the condition for at least twelve months with "disabling effect"), it does not affect the assessment and medicolegal evaluation procedures required by law.

The current rules do not exclude recognition of the conditions of inability, invalidity, etc. It is recalled that citizens aged between 18 and 65 years (and also minors under 18 with persistent difficulties in carrying out age-related tasks and functions) suffering from this (and other conditions) can apply for an invalidity/inability assessment and for recognition of "handicap" (see below), and thus for the benefits granted under Italian

Law 104/92 to the disabled person and their family. According to this law, those with forms of headache or migraine severe enough to cause them serious difficulties with learning, in their social life, and in their working life, can be considered "handicapped" (as per the terminology used in the 1992 law and revised, as a concept, by the World Health Organization (WHO) in 1999).

The term "handicap", used by the legislator in law no. 104/92, has instrumental value as it differentiates and underlines the complementarity of this measure with respect to the protection provided for by civil invalidity law (which specifically concerns employable individuals), and also has a "distinctive" purpose, in that it responds to a specific request advanced, during the drafting of the law, by an association for the families of people with intellectual and/or relational disability (ANFASS). The term is, moreover, inconsistent with the doctrinal and operational tradition of legal medicine in Italy, which uses the categories incapacity, invalidity, inability (variously defined according to application needs, "adapted", or *ex lege*), and is now even more decisively superseded at international level (see the United Nations Convention on the Rights of Persons with Disabilities, 11 December 2006; Italian Law no. 18 of 3 March 2009).

In this regard, it is noted that pediatric headache patients are a crucially important category, given the possible recognition not only of direct benefits to these young patients, but also of secondary benefits to family members, necessary to improve their care.

It is also noted that the civil invalidity recognition procedure is triggered by submission of the certification to INPS (the body that since 2009 – Legislative degree no. 78 of July 1, 2009, art 20; Law no. 102 of 3 August 2009; INPS decision no. 189 of 20 October 2009 – has been responsible for verifying the civil invalidity/handicap application evaluations and ascertainments preliminarily carried out by the Italian national health system's Legal Medicine Services department). The document is sent by the general practitioner, who must attach, in addition to their own certification, the specialist one indicating the specific pathological condition, which in the case of headache, is issued by the accredited center mentioned in the law.

Q12 - *Who must be contacted to access the legal protections envisaged in cases of disability?*

A12 - The actual existence of civil invalidity and "handicap" (see comment in A11) must be ascertained and confirmed by a specialist medicolegal body, primarily by the medicolegal commission of first instance, which must also specify its "extent" (i.e., define the "percentage") for determining the protection measures. This body then sends its conclusions to the INPS second instance commission. The percentages of disability (defined by a legal table) must reflect what is described in the certification, which in turn must contain adequate descriptive clarification (a complete and detailed medical history, including onset, frequency and trend over the years, treatments adopted and clinical efficacy/response rates, possible presence of comorbidities, possible drug abuse, drug resistance, number of drug withdrawal attempts made, if any, and any aspects that may affect the condition, enhancing and aggravating its impact on the patient's social life).

In the presence of the necessary requisites, and when requested, the patient's medical doctor (GP or specialist) is also required to draw up a certification to be sent, in the first instance, to INPS, requesting recognition of temporary incapacity for work and, therefore, the use of paid absence due to illness.

It is good to inform patients that the protection measures provided by the Italian legal system in the event of "disability" are not limited to civil invalidity/"handicap", but also cover cases of "pensionable invalidity" (INPS), "occupational disease" (INAIL), and "*causa di servizio*", i.e., diseases contracted in the workplace (CMO), in relation to which patients should be referred to the various specific associations for the disabled (ANMIC, for example).

Conclusions and perspectives

In line with requests made by patient associations and scientific societies, the legislator has decided to include chronic primary headache, including high-frequency migraine, in the category of social diseases. The decrees for the implementation of law 81/2020 have only recently been approved, probably in part due to problems related to the pandemic. This

period of time has, however, allowed us to prepare for the day when this law will be applied, enabling us to identify the best ways to ensure that patients who are entitled to take advantage of the legal benefits are able to do so. Thanks to the product of our work, doctors can immediately start implementing all the procedures and good clinical practices necessary to highlight the patient's real conditions in the most objective and reproducible way possible, and provide them with the appropriate support to obtain all the necessary legal protections. Tables I and II summarize the main questions and answers concerning application of the new law.

The Committee has decided to hold periodic meetings to verify the impact of this document, so as to be able to update it in the light of critical issues emerging in its practical application, and also on the basis of new technical-scientific evidence.

To date, the following are considered to be the main advances that might, in the future, further im-

Table 1. Summary of questions / answers 1-6 regarding law no. 81 of 14/7/2020 (Consent document and recommendations)

Q1- *What are the forms of chronic headache covered by Law no. 81 of 14 July 2020 containing "Provisions for the recognition of chronic primary headache as a social disease" (Italian Official Gazette, no. 188 of 28 July 2020, entry into force 12 August 2020)?*

A1-The law recognizes, as *chronic headache*, clinical forms that do not have a primary etiology or pathogenesis attributable another clinical or pathological situation (i.e., that are not secondary to other nosologically defined conditions, e.g., neoplasms, traumas, etc.), and that in terms of the quantity of clinical manifestations, can objectively be said to occur on at least 15 days a month. These forms are: chronic and high-frequency migraine; chronic daily headache with or without overuse of analgesic drugs; chronic cluster headache; chronic paroxysmal hemicrania; short-lasting unilateral neuralgiform headache attacks with conjunctival injection and tearing (SUNCT); continuous migraine.

Q2 - *What are the requirements?*

A2 - Chronic primary headache, of any form, is recognized as a social disease (see Italian Ministerial Decree of 12 June 1972 and subsequent amendments) if it has been diagnosed for at least one year by a headache specialist at an accredited center for the diagnosis and treatment of headaches, who certifies its disabling effect.

Q3 - *How should the diagnosis be confirmed?*

A3 - For all the forms of primary chronic headache listed, the diagnosis is exclusively clinical and not instrumental. Thus, it is based on the patient's history, confirmed by a clinical neurological examination found to be negative for any specific pathology that might justify the clinical picture, and, finally, supported by 12 months of monitoring and observation at the headache center in question.

Q4 - *Is monitoring with diary cards necessary?*

A4 -a) Headache centers always require patients to keep a headache diary, which is a fundamentally important instrument in this setting in order to confirm the diagnosis and the presence of the headache on more than 15 days per month

b) In addition to diaries, the specialist should administer the patient specific tests and validated and shared assessment and quantification tools in order to document the impact of the clinical form on the patient's daily life.

Q5 - *Are instrumental checks or diagnostic tests necessary?*

A5 - Already mentioned above (see A3), specific tests will be carried out only in the presence of so-called sentinel symptoms, in order to rule out a secondary nature of the headache. According to anamnestic data on comorbidities, a patient may need to undergo specific tests to better define and stage the same.

Q6 - *Who issues the certification?*

A6 - The specialist at the accredited center who makes the diagnosis and manages the case over the following 12 months.

Table 2. Summary of questions / answers 7-12 regarding law no. 81 of 14/7/2020 (Consent document and recommendations)

Q7 - *What comorbidities should be considered?*
A7- The law does not specify this; however, in accordance with good clinical practice, specific internal medical/ metabolic, neurological, inflammatory, intestinal, and psychiatric comorbidities must always be investigated, as well as the presence of sleep disorders and the presence of disorders of the cervico-mandibular complex, as well as other types of cranial and orofacial pain.
Q8 - *How should comorbidities be investigated?*
A8 - The specific investigations conducted differ from patient to patient, and should be prescribed in the light of the history and clinical examination. Furthermore, precise classification of the case may require input from other specialists.
Q9 - *Should treatments be considered?*
A9- Therapies must always be taken into consideration. Compatibly with their clinical condition, a patient must have exhausted all the main therapeutic options for their headache indicated by reference guidelines, and in the case of medication overuse must have made at least one attempt to break the habit. In addition, drug resistance and drug intolerance must be documented.
Q10 - *Should the patient's age be considered, and whether or not they work?*
A10- When a patient struggles to perform, or is unable to perform, their work and/or routine daily activities, this aspect must be given maximum consideration both in the descriptive diary phase, and in the assessment phase.
Q11 - *What procedures must be followed to obtain a disability assessment?*
A11 - It should be remembered that recognition of a "social disease" does not imply automatic recognition of "invalidity/disability". The procedures established by the laws governing the question must therefore be followed.
Q12 - *Who must be contacted to access the legal protections envisaged in cases of disability?*
A12 - The actual existence of the invalidity must be ascertained and confirmed by a specialist medicolegal body, primarily the medicolegal commission of first instance, which must also specify its "extent" (i.e., define the "percentage") for determining the protection provisions. This body then sends its conclusions to the INPS second instance commission. In the presence of the necessary requisites, and if requested, the headache patient's medical doctor (GP or specialist) is also required to draw up a certification to be sent to INPS requesting recognition of temporary incapacity for work and, therefore, the use of paid absence due to illness.

prove the evaluation of the disability produced by chronic primary headaches:

a. contributions to the nosography, allowing for the inclusion of other forms of chronic primary headache;
b. identification of a group of scales useful for defining all the patient profiles relevant to the problem in question;
c. unambiguous definition of the concept of refractoriness to treatments that considers new therapeutic approaches, timing and dosages for efficacy evaluation, and profiles (of comorbidity or intolerance) necessitating exclusion from treatments;
d. identification of biochemical, genetic, neurophysiological or functional neuroimaging markers that can help to objectively demonstrate the involvement of pain control systems, correlating this with the severity of the clinical picture.

In addition to an implementation phase of the document, the Committee will also try to promote, where possible, research that might make further contributions within this field.

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Appendix

*** COMPLETE ACT ***

LAW 14 July 2020, no. 81

Provisions for the recognition of chronic primary headache as a social disease. (20G00100) (GU no.188 of 28-7-2020)

Effective on: 12-8-2020

The Chamber of Deputies and the Senate of the Republic have approved;

THE PRESIDENT OF THE REPUBLIC

Promulgates

the following law:

Art. 1

1. Chronic primary headache, present for at least one year in the patient, as ascertained on the basis of a diagnosis made by a headache specialist at an accredited center for the diagnosis and treatment of headaches, certifying its disabling effect, is recognized as a social disease, for the purposes referred to in paragraph 2, in the following forms:

a) chronic and high-frequency migraine;

b) chronic daily headache with or without overuse of analgesic drugs;

c) chronic cluster headache;

d) chronic paroxysmal hemicrania;

e) short-lasting unilateral neuralgiform headache with conjunctival injection and tearing;

f) continuous migraine.

2. By decree of the Minister of Health, to be adopted within one hundred and eighty days from the date of entry into force of this law, subject to an agreement ratified in the Permanent Conference for relations between the State, the regions and the autonomous Provinces of Trento and Bolzano, projects are identified, generating no new or increased burdens on public finances, aimed at experimenting innovative methods of taking care of people with headache in the forms referred to in paragraph 1, as well as the criteria and methods according to which the regions shall implement the said projects.

This law, bearing the state seal, will be included in the official collection of the normative acts of the Italian Republic. It is mandatory for anyone responsible to observe it and to ensure that it is enforced as state law.

Date in Rome, July 14, 2020

MATTARELLA

Conte, President of the Council of Ministers

Seen, the Keeper of the Seals: Bonafede

Official Bulletin of the Lombardy Region

Ordinary Series - No. 3 - January 15, 2007
(BUR20070118) (3.1.0 / 3.2.0)

Circ. December 14, 2006 - no. 30

Operational indications for the assessment of headache in the context of civil invalidity

To Local Health Authority (ASL) General Directors
To ASL Legal Medicine Service Managers

THEIR OFFICES

Introduction

The assessment of invalidity is an activity of particular social-health interest, falling within the scope of the Essential Levels of Assistance.

The Region is among the administrations most involved in this sphere by lawmakers, providing governance and control of efficiency and performance quality.

Furthermore, the verification work done by Local Health Authorities (ASL) is a valuable instrument for data collection and monitoring of the state of health of citizens.

The ministerial tables referred to in the Ministerial Decree of 5 February 1992 and the subsequent one of 14 June 1994 constitute the guiding tool for the medicolegal assessments conducted by civil invalidity assessment commissions.

Although these tables constitute an essential legal reference source, they are known to be not only obsolete, but also nosographically incomplete and somewhat "schematic".

The evolution of diagnostic-therapeutic-rehabilitation approaches and the failure to update these tables have made it opportune to develop initiatives for updating them, to provide the commissions with efficient operational conditions that respond to the real needs of this field.

To this end, the General Directorate for Family and Social Solidarity established, by General Director's decree no. 3469 of 28 March 2006, a Working Group comprising a representative of the General Directorate for the Family and Social Solidarity, the General Health Directorate, a university lecturer/external expert, and ASL area managers.

The percentage assessment of headaches in the context of civil invalidity

One of the updating needs envisaged and addressed concerned people with headache syndromes.

The Working Group, having acquired specific elements from experts in the field, developed a grid for assessing these morbid conditions.

Attached hereto is the document produced, to serve as an updating and support tool for civil invalidity assessment commissions.

Thank you for your cooperation.

Yours sincerely,

General Director, Health General Directorate: Carlo Lucchina

General Director, General Directorate for the Family and Social Solidarity: Umberto Fazzone

ATTACHMENTS:

Evaluation of headaches in CI including table

International Classification of Headaches

———— • ————

PERCENTAGE ASSESSMENT OF HEADACHE IN THE CONTEXT OF CIVIL INVALIDITY

The composition of the working group

- *Coordinator – Dr Rosella Petrali, Manager of the Social Welfare System Organizational Unit, General Directorate for the Family and Social Solidarity;*
- *Members:*
  - *Prof. Fabio Buzzi, Director of the Institute of Forensic Medicine of the University of Pavia, scientific consultant;*
  - *Dr. Umberto Genovese, researcher at the Institute of Forensic Medicine, University of Milan;*
  - *Dr. Gian Franco Bertani, officer, Health General Directorate;*
  - *Dr. Alberto Germani, forensic doctor, City of Milan Local Health Authority;*

- *Dr. Paolo Pelizza, forensic doctor, Province of Brescia Local Health Authority;*
- *Dr. Amneris Magella, forensic doctor, Province of Como Local Health Authority;*

• *Secretariat - Dr. Lia Bottini, officer, Social Welfare System Organizational Unit, General Directorate for the Family and Social Solidarity.*

The path to the development of the technical document

Given that the ministerial civil invalidity assessment tables contain no references that can be used, not even analogously, the following work plan was activated:

Nosographic classification of headache, assessment of the degree of invalidity and diagnostic parameters

The Working Group consulted experts working at various headache centers, who provided insights into the epidemiological data, the nosographic classification, the diagnostic process, and the criteria for estimating the severity of the clinical picture.

Percentage grading according to usual tabular schemes

On the basis of all the elements provided, the main clinical pictures of primary headaches (PH) were identified, analyzing and establishing their characteristics in terms of frequency, duration and intensity, and formulating, on the basis of these assumptions, a table which is proposed as a reference guide for the percentage grading of headache in the context of civil invalidity.

To ensure its correct use, the table is supplemented by warnings and recommendations of a medicolegal nature and is completed by bibliographic references.

To complete the information framework and provide support to the commissions, the technical document is supplemented by the International Classification of Headaches.

Terminology and definitions

Frequency:

Medium-low

- up to 3 attacks/month for migraine and tension-type headache
- up to 1 attack in 24 hours for cluster headache for active periods lasting ≤ 1 month
- up to 10% of the day with pain due to paroxysmal hemicrania and trigeminal neuralgia for ≤1 month per year

The assessment table

Primary headache and essential neuralgia

0-15%		***16-30%***	***31-46%***
A) ***Episodic forms with medium-low frequency of attacks and satisfactory response to treatment***	***B1)*** ***Episodic forms with medium-high frequency of attacks and poor response to treatment***	***B2)*** ***Chronic forms with partial response to treatment***	***C)*** ***Chronic forms refractory to treatment***
1) Migraine without and with aura	1) Migraine without and with aura	1) Chronic migraine	1) Chronic migraine
2) Frequent tension-type headache	2) Tension-type headache	2) Chronic daily headache with or without analgesic overuse	2) Chronic daily headache with or without analgesic overuse
3) Episodic cluster headache	3) Episodic cluster headache	3) Chronic cluster headache	3) Chronic cluster headache
4) Episodic paroxysmal hemicrania	4) Episodic paroxysmal hemicrania	4) Chronic paroxysmal hemicrania	4) Chronic paroxysmal hemicrania
		5) SUNCT (short-lasting unilateral neuralgia with conjunctival injection and tearing)	5) SUNCT
		6) Hemicrania continua	6) Hemicrania continua
		7) NDPH (new daily persistent headache)	7) NDPH (new daily persistent headache)
8) Classical trigeminal neuralgia and other neuralgias of the head	8) Classical trigeminal neuralgia and other neuralgias of the head	8) Classical trigeminal neuralgia and other neuralgias of the head	8) Classical trigeminal neuralgia and other neuralgias of the head

Medium-high
- 3 attacks/month for migraine and tension-type headache
- 1 attack in 24 hours for cluster headache with active periods lasting >1 month
- over 10% and up to 30% of the day with pain due to paroxysmal hemicrania and trigeminal neuralgia for >1 month per year

Chronicity
- for migraine and tension-type headache: ≥15 days per month for at least 3 months
- for cluster headache and chronic paroxysmal hemicrania: attacks for at least one year with remissions lasting <1 month
- for trigeminal neuralgia: attacks for at least a year, without remissions lasting more than 1 month

NOTE: SUNCT is rare and the forms described are prevalently chronic. Continuous migraine and NDPH are chronic by definition.

Response to treatments

Satisfactory: headache is reduced by at least 50% with prophylaxis treatment and/or the response to symptoms is complete (significant reduction of symptoms or its disappearance within two hours from intake).

Poor: headache is reduced by <50% after at least 4 treatments with prophylactic drugs of proven efficacy, taken with adequate dosage and duration. The response to symptoms is partial.

Refractory: no benefit to 4 treatments with prophylactic drugs of proven efficacy, taken with adequate dosage and duration.

Comorbidity

In the quantification it is necessary to take into account any comorbidities.

The most frequent comorbidities for migraine are: hypertension, depression, and anxiety.

For tension-type headache: depression, anxiety, psychosocial stress.

Secondary forms of headache

Please refer to the criteria in force for the organic disease causing the headache.

Health documentation

At the current state of knowledge, no investigation has value as a diagnostic test for headache. In fact, the diagnosis is almost always clinical and based on a detailed history and adequate period of observation and treatment.

The need to rigorously define the various forms of headache pathology from a diagnostic point of view therefore requires that the certifications presented to ASL commissions come from headache centers of national standing. Given the need to evaluate the disabling impact of the disease, on the basis of the frequency, duration and intensity of the attacks as well as the therapeutic response, this certification must reflect a period of observation of the case lasting at least one year.

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NOTE TO BIBLIOGRAPHICAL REFERENCES:
Although not expressly provided for in the documentation in return, the group's experts referred to their decades of clinical experience.

INTERNATIONAL CLASSIFICATION OF HEADACHE

In order to facilitate understanding of the diagnostic terms used, an abridged version of the International Classification of Headaches is shown below.

This version has been prepared to facilitate rapid consultation by experienced doctors in the field of headaches and contains the coding of the forms of headache included in the International Classification and the official diagnostic criteria for the main forms of primary headache.

This abridged version is based on the Italian translation of the International Classification produced by the IHS Italian Linguistic Committee. (*Coordinator:* Prof. G. Nappi).

The abridged version shown here does not contain the introductory or explanatory notes and comments that, in many cases, are necessary for correct use of the classification.

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1. MIGRAINE

1.1 Migraine without aura
1.2 Migraine with typical aura
- 1.2.1 Typical aura with migraine headache
- 1.2.2 Typical aura with non-migraine headache
- 1.2.3 Typical aura without headache
- 1.2.4 Familial hemiplegic migraine
- 1.2.5 Sporadic hemiplegic migraine
- 1.2.6 Basilar-type migraine

1.3 Childhood periodic syndromes possible common precursors migraine
- 1.3.1 Cyclical vomiting
- 1.3.2 Abdominal migraine
- 1.3.3 Benign paroxysmal vertigo of childhood

1.4 Retinal migraine
1.5 Complications of migraine
- 1.5.1 Chronic migraine
- 1.5.2 Status migrainosus
- 1.5.3 Persistent aura without infarction
- 1.5.4 Migrainous infarction
- 1.5.5 Migraine-triggered seizure

1.6 Probable migraine
- 1.6.1 Probable migraine without aura
- 1.6.2 Probable migraine with aura
- 1.6.5 Probable chronic migraine

***

1.1 Diagnostic criteria for migraine without aura

A. At least 5 attacks fulfilling criteria B-D
B. Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated)
C. Headache has at least two of the following characteristics:
1. Unilateral location
2. pulsating quality
3. moderate or severe pain intensity
4. aggravation by or causing avoidance of routine physical activity (e.g. walking, climbing stairs)

D. During headache at least one of the following:
1. nausea and/or vomiting
2. photophobia and phonophobia

E. Not attributed to another disorder

1.2 Diagnostic criteria for migraine with typical aura

A. At least 2 attacks fulfilling criterion B
B. Migraine aura fulfilling criteria B and C for one of the subforms 1.2.1-1.2.6
C. Not attributed to another disorder

1.2.1 Diagnostic criteria for typical aura with migraine headache

A. At least 2 attacks fulfilling criteria B-D
B. Aura consisting of at least one of the following, with no motor weakness:
1. fully reversible visual symptoms including positive features (e.g., flickering lights, spots or lines)
2. fully reversible sensory symptoms including positive features (i.e., pins and needles) and/or negative features (i.e., numbness)
3. fully reversible dysphasic speech disturbance

C. At least two of the following:
1. homonymous visual symptoms and/or unilateral sensory symptoms
2. at least one aura symptom develops gradually over ≥5 minutes and/or different aura symptoms occur in succession over ≥5 minutes
3. each symptom lasts ≥5 minutes and ≤60 minutes

D. A headache fulfilling criteria B-D for 1.1 *Migraine without aura* begins during the aura or follows aura within 60 minutes
E. Not attributed to another disorder

1.2.2 Diagnostic criteria for typical aura with non-migraine headache

A. At least 2 attacks fulfilling criteria B-D
B. Aura consisting of at least one of the following, but no motor weakness:
1. fully reversible visual symptoms including positive features (e.g., flickering lights, spots or lines) and/or negative features (i.e., loss of vision)
2. fully reversible sensory symptoms including positive features (i.e., pins and needles) and/or negative features (i.e., numbness)
3. fully reversible dysphasic speech disturbance

C. At least two of the following:
1. homonymous visual symptoms and/or unilateral sensory symptoms
2. at least one aura symptom develops gradually over ≥5 minutes and/or different symptoms occur in succession over ≥5 minutes
3. each symptom lasts ≥5 minutes and ≤60 minutes

D. Headache that does not fulfill criteria B-D criteria for 1.1 *Migraine without aura* begins during the aura or follows aura within 60 minutes
E. Not attributed to another disorder

1.2.3 Diagnostic criteria for typical aura without headache

A. At least 2 attacks fulfilling criteria B-D
B. Aura consisting of at least one of the following, but no motor weakness:
1. fully reversible visual symptoms including positive features (e.g., flickering lights, spots or lines) and/or negative features (i.e., loss of vision)
2. fully reversible sensory symptoms including positive features (i.e., pins and needles) and/or negative features (i.e., numbness)

C. At least two of the following:
1. homonymous visual symptoms and/or unilateral sensory symptoms
2. at least one aura symptom develops gradually over ≥5 minutes and/or different aura symptoms occur in succession in ≥5 minutes
3. each symptom lasts ≥5 minutes and ≤60 minutes

D. Headache does not occur during aura nor follow aura within 60 minutes
E. Not attributed to another disorder

1.2.4 Diagnostic criteria for familial hemiplegic migraine

A. At least 2 attacks fulfilling criteria B and C
B. Aura consisting of fully reversible motor weakness and at least one of the following:
1. fully reversible visual symptoms including positive features (e.g., flickering lights, spots or lines) and/or negative features (i.e., loss of vision)
2. fully reversible sensory symptoms including positive features (i.e., pins and needles) and / or negative features (i.e., numbness)
3. fully reversible dysphasic speech disturbance

C. At least two of the following:
1. at least one aura symptom develops gradually over ≥5 minutes and/or different symptoms occur in succession in ≥5 minutes
2. each aura symptom lasts ≥5 minutes and <24 hours
3. headache fulfilling criteria B-D for 1.1 *Migraine without aura* begins during the aura or follows onset of aura within 60 minutes

D. At least one first- or second-degree relative has had aura attacks fulfilling these criteria A-E
E. Not attributed to another disorder

1.2.5 Diagnostic criteria for sporadic hemiplegic migraine

A. At least 2 attacks fulfilling criteria B and C
B. Aura consisting of fully reversible motor weakness and at least one of the following:
1. fully reversible visual symptoms including positive features (e.g., flickering lights, spots or lines) and/or negative features (i.e., loss of vision)
2. fully reversible sensory symptoms including positive features (i.e., pins and needles) and/or negative features (i.e., numbness)
3. fully reversible dysphasic speech disturbance

C. At least two of the following:
1. at least one aura symptom develops gradually over ≥5 minutes and/or different symptoms occur in succession over ≥5 minutes

2. each aura symptom lasts ≥5 minutes and <24 hours
3. headache fulfilling criteria B-D for 1.1 *Migraine without aura* begins during the aura or follows the onset of aura within 60 minutes

D. No first- or second-degree relative has attacks fulfilling these criteria A-E
E. Not attributed to another disorder

1.2.6 Diagnostic criteria for basilar-type migraine

A. At least 2 attacks fulfilling criteria B-D
B. Aura consisting of at least two of the following fully reversible symptoms, but no motor weakness:

1. dysarthria
2. vertigo
3. tinnitus
4. hypacusia
5. diplopia
6. visual symptoms simultaneously in both temporal and nasal fields of both eyes
7. ataxia
8. decreased level of consciousness
9. simultaneously bilateral paraesthesias

C. At least one of the following:

1. at least one aura symptom develops gradually over ≥5 minutes and/or different aura symptoms occur in succession over ≥5 minutes
2. each aura symptom lasts ≥5 and ≤60 minutes D. Headache fulfilling criteria B-D for 1.1 *Migraine without aura* begins during the aura or follows aura within 60 minutes

E. Not attributed to another disorder

1.3.1 Diagnostic criteria for cyclical vomiting

A. At least 5 attacks fulfilling criteria B and C
B. Episodic attacks, stereotypical in the single patient, of intense nausea and vomiting lasting from 1 hour to 5 days
C. Vomiting during the attack occurs at least 4 times/hour for at least 1 hour
D. Symptom-free between attacks
E. Not attributed to another disorder

1.3.2 Diagnostic criteria for abdominal migraine

A At least 5 attacks fulfilling criteria B-D
B. Attacks of abdominal pain lasting 1-72 hours (untreated or unsuccessfully treated)
C. Abdominal pain has all of the following characteristics:

1. midline location, periumbilical or poorly localised
2. dull or "just sore" quality
3. moderate or severe intensity

D. During abdominal pain, least two of the following symptoms:

1. anorexia
2. nausea
3. vomiting
4. pallor

E. Not attributed to another disorder

1.3.3 Diagnostic criteria for benign paroxysmal vertigo of childhood

A. At least 5 attacks fulfilling criterion B
B. Multiple episodes of severe vertigo, occurring without warning and resolving spontaneously after minutes to hours
C. Normal neurological examination and audiometric and vestibular functions between attacks
D. Normal electroencephalogram

1.4 Diagnostic criteria for retinal migraine

A. At least 2 attacks fulfilling criteria B and C
B. Fully reversible monocular positive and/or negative visual phenomena (e.g., scintillations, scotomata or blindness), confirmed by an examiner during the attack or (after proper instruction) by the patient's drawing of a monocular field defect during an attack
C. Headache fulfilling criteria B-D for 1.1 *Migraine without aura* begins during the visual symptoms or follows them within 60 minutes
D. Normal ophthalmological examination between attacks
E. Not attributed to another disorder

1.5.1 Diagnostic criteria for chronic migraine

A. Headache fulfilling criteria C and D for 1.1 *Migraine without aura* on ≥15 days/month for >3 months
B. Not attributed to another disorder

1.5.2 Diagnostic criteria for status migrainosus

A. The present attack in a patient with 1.1 *Migraine without aura* is typical of previous attacks, except for its duration

B. Headache has both of the following features:
1. unremitting for ≥72 hours
2. severe intensity

C. Not attributed to another disorder

1.5.3 Diagnostic criteria for persistent aura without infarction

A. The present attack in a patient with 1.2 *Migraine with aura* is typical of previous attacks except that one or more aura symptoms persists for >1 week

B. Not attributed to another disorder

1.5.4 Diagnostic criteria for migrainous infarction

A. The present attack in a patient with 1.2 *Migraine with aura* is typical of previous attacks except that one or more aura symptoms persists for >60 minutes

B. Neuroimaging demonstrates ischaemic infarction in a relevant area

C. Not attributed to another disorder

1.5.5 Diagnostic criteria for migraine-triggered seizure

A. Migraine fulfilling criteria for 1.2 *Migraine with aura*

B. A seizure fulfilling diagnostic criteria for one type of epileptic attack occurs during or within 1 hour after a migraine aura

1.6.1 Diagnostic criteria for probable migraine without aura

A. Attacks fulfilling all but one of criteria A-D for 1.1 *Migraine without aura*

B. Not attributed to another disorder

1.6.2 Diagnostic criteria for probable migraine with aura

A. Attacks fulfilling all but one of criteria A-D for 1.2 *Migraine with aura* or any of its subforms

B. Not attributed to another disorder

1.6.5 Diagnostic criteria for probable chronic migraine

A. Headache fulfilling criteria C and D for 1.1 *Migraine without aura* on ≥15 days/month for > 3 months

B. Not attributed to another disorder, but there is, or has been within the last 2 months, medication overuse fulfilling criterion B for any of the subforms of 8.2 *Drug overuse headache*

2. TENSION-TYPE HEADACHE

2.1 Infrequent episodic tension-type headache
2.1.1 Infrequent episodic tension-type headache associated with pericranial tenderness
2.1.2 Infrequent episodic tension-type headache not associated with pericranial tenderness
2.2 Frequent episodic tension-type headache
2.2.1 Frequent episodic tension-type headache associated with pericranial tenderness
2.2.2 Frequent episodic tension-type headache not associated with pericranial tenderness
2.3 Chronic tension-type headache
2.3.1 Chronic tension-type headache associated with pericranial tenderness
2.3.2 Chronic tension-type headache not associated with pericranial tenderness
2.4 Probable tension-type headache
2.4.1 Probable infrequent episodic tension-type headache
2.4.2 Probable frequent episodic tension-type headache
2.4.3 Probable chronic tension-type headache

***

2.1 Diagnostic criteria for infrequent episodic tension-type headache

A. At least 10 episodes occurring on <1 day per month on average (<12 days per year) and fulfilling criteria B-D

B. Headache lasting from 30 minutes to 7 days

C. Headache has at least two of the following characteristics:
1. Bilateral localization
2. pressing/tightening (non-pulsating) quality
3. mild or moderate intensity
4. is not aggravated by routine physical activity, such as walking climbing or climbing stairs

D. Both of the following:
1. no nausea or vomiting (anorexia may occur)
2. no more than one of photophobia or phonophobia

E. Not attributed to another disorder

2.1.1 Infrequent episodic tension-type headache associated with pericranial tenderness

A. Episodes fulfilling criteria A-E for 2.1 *Infrequent episodic tension-type headache*

B. Increased pericranial tenderness on manual palpation

2.1.2 Infrequent episodic tension-type headache not associated with pericranial tenderness

A. Episodes fulfilling criteria A-E for 2.1 *Infrequent episodic tension-type headache* B. No increased pericranial tenderness

2.2 ***Diagnostic criteria for headache frequent episodic tension-type headache***

A. At least 10 episodes occurring ≥1 but <15 days per month for at least 3 months (≥12 and <180 days per year) and meeting criteria B-D

B. Headache lasting from 30 minutes to 7 days

C. Headache has at least two of the following characteristics:

1. bilateral locaation
2. pressing/tightening (non-pulsating) quality
3. mild or moderate intensity
4. not aggravated by routine physical activity, such as walking climbing or climbing stairs

D. Both of the following:

1. no nausea or vomiting (anorexia may occur)
2. no more than one of photophobia or phonophobia

E. Not attributed to another disorder

2.2.1 Frequent episodic tension-type headache associated with pericranial tenderness

A. Episodes fulfilling criteria A-E for 2.2 *Frequent episodic tension-type headache*

B. Increased pericranial tenderness on manual palpation

2.2.2 Frequent episodic tension-type headache not associated with pericranial tenderness

A. Episodes fulfilling criteria A-E for 2.2 *Frequent episodic tension-type headache*

B. No increased pericranial tenderness

2.3 Diagnostic criteria for chronic tension-type headache

A. Headache occurring on ≥15 days per month for >3 months (≥180 days per year) and fulfilling criteria B-D

B. Headache lasts hours or may be continuous

C. Headache has at least two of the following characteristics:

1. Bilateral location
2. pressing/tightening (non-pulsating) quality
3. mild or moderate intensity
4. not aggravated by routine physical activity such as walking or climbing stairs

D. Both of the following:

1. no more than one of photophobia, phonophobia or mild nausea
2. neither moderate or severe nausea nor vomiting

E. Not attributed to another disorder

2.3.1 Chronic tension-type headache associated with pericranial tenderness

A. Headache fulfilling criteria A-E for 2.3 *Chronic tension-type headache*

B. Increased pericranial tenderness on manual palpation

2.3.2 Chronic tension-type headache not associated with pericranial tenderness

A. Headache fulfilling criteria A-E for 2.3 *Chronic tension-type headache*

B. No increased pericranial tenderness

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3. CLUSTER HEADACHE AND OTHER TRIGEMINAL AUTONOMIC CEPHALALGIAS

3.1 Cluster headache
3.1.1 Episodic cluster headache
3.1.2 Chronic cluster headache
3.2 Paroxysmal hemicrania
3.2.1 Episodic paroxysmal hemicrania
3.2.2 Chronic paroxysmal hemicrania
3.3 Short-lasting unilateral neuralgiform headache attacks with conjunctival injection and tearing (SUNCT)
3.4 Probable trigeminal autonomic cephalalgia
3.4.1 Probable cluster headache
3.4.2 Probable paroxysmal hemicrania
3.4.3 Probable SUNCT

3.1 Diagnostic criteria for cluster headache

A. At least 5 attacks fulfilling criteria B-D

B. Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15-180 minutes if untreated

C. Headache is accompanied by at least one of the following:

1. ipsilateral conjunctival injection and/or lacrimation
2. ipsilateral nasal congestion and/or rhinorrhoea
3. ipsilateral eyelid oedema
4. ipsilateral forehead and facial sweating
5. ipsilateral myosis and/or ptosis
6. a sense of restlessness or agitation

D. Attacks have a frequency from one every other day to 8 per day

E. Not attributed to another disorder

3.1.1 Diagnostic criteria for episodic cluster headache

A. Attacks fulfilling criteria A-E for 3.1 *Cluster headache*

B. At least two cluster periods lasting 7-365 days and separated by pain-free remission periods of ≥1 month

3.1.2 Diagnostic criteria for chronic cluster headache

A. Attacks fulfilling criteria A-E for 3.1 *Cluster headache*

B. Attacks recur over >1 year without remission periods or with remission periods lasting <1 month

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8.2 MEDICATION-OVERUSE HEADACHE

8.2 Diagnostic criteria for medication-overuse headache

A. Headache present on > 15 days/month and fulfilling criteria C and D

B. Regular overuse for > 3 months of one or more drugs that may be taken for acute and/or symptomatic treatment of headache

C. Headache has developed or markedly worsened during ***overuse*** of drug (s)

D. Headache resolves or reverts to its previous pattern within 2 months after discontinuation of the overused drug(s) used excessively

8.2.1 Diagnostic criteria for ergotamine-overuse headache diagnostic criteria

A. Headache fulfilling criteria A, C and D for 8.2 *Medication-overuse headache*

B. Ergotamine intake on ≥10 days/month for ≥ 3 months

8.2.2 Diagnostic criteria for tripan-overuse headache

A. Headache fulfilling criteria A, C and D for 8.2 *Medication-overuse headache*

B. Triptan intake (any formulation) on ≥10 days/month on a regular basis for ≥3 months

8.2.3 Diagnostic criteria for analgesic-overuse headache

A. Headache fulfilling criteria A, C and D for 8.2 *Medication-overuse headache*

B. Intake of simple analgesics on ≥15 days/month1 for >3 months

8.2.4 Diagnostic criteria for opioid-overuse headache

A. Headache fulfilling criteria A, C and D for 8.2 *Medication-overuse headache*

B. Opioid intake on ≥10 days/month for > 3 months

8.2.5 Diagnostic criteria for combination medication-overuse headache

A. Headache fulfilling criteria A, C and D for 8.2 *Medication overuse headache*

B. Intake of combination medications on ≥10 days/month for >3 months

8.2.6 Diagnostic criteria for symptomatic drug overuse headache in combination

A. Headache fulfilling criteria A, C and D for 8.2 *Use headache excessive medication*

B. Regular intake of any combination of ergotamines, triptans, analgesics, or opioids for > 10 days per month for > 3 months, in the absence of excessive use of the individual classes

8.2.7 Headache due to overuse of other drugs

A. Headache meeting criteria A, C and D for 8.2 *Medication-overuse headache*

B. Regular overuse for > 3 months of a different drug from those listed above.

Agreement between the Government, the Regions and the autonomous Provinces of Trento and Bolzano on the Health Minister's draft decree, implementing law no. 81 of 14 July 2020, on the activation of regional projects aimed at testing innovative methods for the care of people suffering from chronic primary headache

(approved on 13 February, 2023)

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ATTACHMENT 1
Health Ministry

Guidelines for the realization of regional projects aimed at testing innovative methods for the care of people with chronic primary headache
pursuant to law no. 81 of 14 July 2020

Premise

Headache is a pain symptom in the cranial region that can manifest itself as an isolated attack or with a wider range of disturbances.

In 2018, the *International Classification of Headache Disorders-3* (ICHD-3) divided headache into 14 different types, each with numerous subclasses. The ICHD-3 codes and diagnoses are reported in Table I, attached (*N.B.: see instead: ICDH-3, www. https://ichd-3.org*).

Within this classification, headaches are mainly divided into *primary headaches*, i.e., conditions in which the headache is the main symptom and cannot be attributed to a specific known cause, and *secondary headaches*, i.e., conditions in which the headache is attributed and temporally related to a set of known specific disorders.

The primary headaches

1. Migraine
2. Tension-type headache
3. Trigeminal autonomic cephalalgias
4. Other primary headache disorders

The secondary headaches

5. Headache attributed to trauma or injury to the head and/or neck
6. Headache attributed to cranial or cervical vascular disorder
7. Headache attributed to non-vascular intracranial disorder
8. Headache attributed to a substance or its withdrawal
9. Headache attributed to infection
10. Headache attributed to disorder of homeostasis
11. Headache or facial pain attributed to disorder of the cranium, neck, eyes, ears, nose, sinuses, teeth, mouth or other facial or cranial structure
12. Headache attributed to psychiatric disorder

The World Health Organization (WHO), referring to the Global Burden of Disease study evaluations, ranks headache 2nd among all diseases that cause disability (GBD 2017), and as the leading cause of disability in subjects under the age of 50.

This disease can cause significant losses of productivity linked to affected persons' prolonged absences from work, and it can be a risk factor for other pathological conditions. In fact, the WHO has recognized headache among the diseases with a high social and health impact (World Health Organization, The World Health Report 2001).

According to the YLDs (Years Lived with Disability) parameter, headache is second, after low back pain, in the ranking of the 10 most disabling diseases, both in the world and in Italy, across all age groups, and in both sexes (Vos et al., 2017).

Headache can therefore be considered a painful and invalidating disease, with headache disorders giving rise to personal suffering, impaired quality of life and financial costs for those affected. Repeated headache attacks often disrupt family, social and work life, and can predispose the individual to other illnesses, such as anxiety and depression, which are significantly more common in people with migraine than in healthy individuals.

Data reported in the scientific literature show that headache disorders are a public health problem,

given the associated disability and financial costs to society. Indeed, headache disorders are most troublesome in the productive years (late teens to 50s) and estimates of their financial cost to society, mainly from lost work hours and reduced productivity, are considerable. The WHO has found that in the UK, for example, around 25 million working or school days are lost each year due to migraine alone.

Furthermore, in a WHO survey, it was found that many individuals suffering from headache do not receive effective treatment; in the United States of America and the United Kingdom, for example, only half of those identified with migraine had seen a doctor for headache-related reasons in the twelve months prior to the survey and only two-thirds had received a correct diagnosis; most depended solely on over-the-counter drugs.

Finally, it appears that, worldwide, a large number of people suffering from headache are not diagnosed and not treated for the disease.

Headache disorders are not recognized by the community as serious since they are mostly episodic, do not cause death, and are not contagious. Low specialist consultation rates in developed countries suggest that many affected people are unaware of the existence of effective treatments.

An atlas of headache disorders, created in 2011 by the WHO and a charitable organization called *Lifting the Burden*, reports that in a year, 50.5% of people in the world are affected by headache: migraine in 11.2% of cases, tension-type headache in 50%, medication-overuse headache in 3-4%, and other headaches in the rest. In particular, in Europe, 1 million people are having a migraine attack at any given time, and 190 million working days are lost every year for this reason. Also according to the atlas, the cost per year for a patient with migraine is 1,177 euros, 300 euros for a patient with tension-headache, and 3,444 euros for a patient with medication-overuse headache.

Recent studies show that primary headache worsens following coronavirus disease (COVID-19) and occurs de novo post-infection in subjects who did not previously suffer from it.

Guidelines for regional projects

This technical document represents, for the Regions, a useful tool for planning and activating projects designed to test innovative methods for the care of people affected by chronic primary headache in the forms shown in the following table.

Chronic primary headaches

- Chronic and high-frequency migraine
- Chronic daily headache with or without overuse of analgesic drugs
- Chronic cluster headache
- Chronic paroxysmal hemicrania
- Short-lasting unilateral neuralgiform headache attacks with conjunctival injection and tearing, and continuous migraine

Such projects are therefore aimed **at patients with chronic primary headache, diagnosed by a headache specialist at an accredited center for the diagnosis and treatment of headaches, who certifies its disabling effect.**

The Regions are invited to develop, according to the project sheet shown below, projects aimed at improving the management of people affected by the aforementioned forms of chronic primary headache in order to achieve the following objectives, namely to:
-launch/implement, at regional level, innovative models of patient care, through the development of integrated diagnostic and treatment pathways in order to structure a network of collaboration between the various professionals (level II headache center specialist, outpatient specialist, general practitioner, emergency room doctors, etc.);

- envisage/implement the involvement of specialists from other disciplines, to be included in the treatment pathway on the basis of the patient's needs (gynecologists, psychologists, etc.);
- carry out specific training courses for healthcare personnel;
- promote information and guidance events for citizens;
- support research in the field.

Regions, through their own projects, may reach one or more of the following results:
- guaranteeing equal access to care:
- ensuring timely access to the treatment pathway;
- developing specific diagnostic-therapeutic pathways for these patients;
- building a regional disease network that interfaces with the various regional diagnostic-therapeutic pathways and with the headache networks of the other regions;
- enhancing interaction between the various professionals;
- homogenizing and standardizing professional procedures;
- developing adequate information and effective communication with citizens;
- improving knowledge of headache, on aspects such as diagnostic criteria, treatments and care, and also epidemiology;
- promoting cooperation between institutions, patient associations, and all the professionals involved;
- reducing the economic impact on the health system and society.

The project sheet, completed in every field, must be submitted, together with a resolution or equivalent statement of approval, to the Ministry of Health, General Directorate of Healthcare Planning, no later than 13 December 2023.

The project activities must be completed no later than 31 December 2024.

By 31 January 2025, the Regions are required to transmit to the Ministry of Health, General Directorate of Healthcare Planning, together with a resolution or equivalent statement of approval, a report on the results achieved, completing all the fields of the relevant form, shown below. In particular they must:
- indicate the financial resources used to carry out the project, specifying whether the Region has added resources of its own;
- describe the reference context and current experiences at regional level, and report the main epidemiological data and types of care/services already present before the start of the project;
- submit, for the single project objectives, numerical values referring to the expected result indicators;
- indicate any sustainability of the project, indicating whether, at the end of the project, the Region will continue the activities undertaken with its own resources;
- specify other settings or contexts to which the project or part of it may be transferable, or in which it may be replicable;
- identify the most relevant critical issues faced and the solutions adopted.

Procedures for submitting projects

The Regions submit the resolution of the Regional Council or equivalent statement approving the project, no later than 31 December 2023, to the Ministry of Health, General Directorate of Healthcare Planning, by certified e-mail (dgprog@postacert.sanita.it).

The project is prepared by the Regions according to the "project sheet" below.

The Ministry of Health, General Directorate of Healthcare Planning, evaluates the projects and requests, if necessary, additions or clarifications. Therefore, projects are considered approved if no additions or clarifications are requested within 60 days of the date of receipt of the documentation.

The regional projects must be concluded no later than 31 December 2024.

The Regions, within 31 days of the conclusion of the project activities (31 January 2025), send the Ministry of Health, General Directorate of Healthcare Planning (dgprog@postacert.sanita.it), a report illustrating the activities implemented and the "results achieved form", shown below.

The Ministry of Health, General Directorate of Healthcare Planning, carries out the final assessment of the results achieved on the basis of the reports and result sheets presented by the Regions, reserving the right to request additions and clarifications.

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