



Title:

**Standard procedure for diagnosis  
and comprehensive health care management of  
an adult with transsexualism (F64.0)**

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Ministry of Health of the Slovak Republic pursuant to § 45 (1) (c) of Act 576/2004  
On health care, services related to the provision of health care and on amendments and supplements  
to certain acts, as amended, issues a standard procedure:

### **Standard procedure for the diagnosis and comprehensive management of health care of an adult with transsexualism (F64.0)**

<b>SP nu mb er</b>	<b>Date of submission to the Commission of the Ministry of Health of the Slovak Republic for STDs</b>	<b>Status</b>	<b>Effective date of approval by the Minister of Health of the Slovak Republic</b>
0279	2 February 2023	Approved by	3 March 2023

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**Supported by a grant** from the OP Human Resources of the Ministry of Labour and Social Policy of the Slovak Republic NFP entitled: "Creation of new and innovative procedures of standard clinical practices and their introduction into medical practice" (code NFP312041J193)

## Keywords

transsexualism, transition, gender dysphoria, gender non-conformity

## List of abbreviations

<b>AFAB</b>	individuals with female sex assigned at birth (Individuals Assigned as Female at Birth)
<b>AMAB</b>	individuals with male sex assigned at birth (Individuals Assigned as Male at Birth)
<b>APA</b>	American Psychiatric Association
<b>BNSTc</b>	the central nucleus of the bed nucleus in the stria terminalis (Central Nucleus of the Bed Nucleus of Stria Terminalis)
<b>Ca</b>	Calcium
<b>dg.</b>	Diagnosis
<b>DHEA -S</b>	dehydroepiandrosterone sulfate
<b>DM type 2</b>	diabetes mellitus type 2
<b>DSD</b>	Disorders of Sex Development
<b>DSM</b>	The Diagnostic and Statistical Manual of Mental Disorders (The Diagnostic and Statistical Manual of Mental Disorders)
<b>DSM -IV</b>	4th revision of the Diagnostic and Statistical Manual of Mental Disorders (The Diagnostic and Statistical Manual of Mental Disorders, fourth revision)
<b>DSM -5</b>	5. revision of the Diagnostic and Statistical Manual of Mental Disorders (The Diagnostic and Statistical Manual of Mental Disorders, 5th revision)
<b>E 2</b>	estradiol
<b>ENIGI</b>	European Network for the Investigation of Gender Incongruence
<b>ECHR</b>	European Court of Human Rights
<b>F64.0</b>	diagnostic unit transsexualism according to ICD-10
<b>FSH</b>	follicle stimulating hormone
<b>FtM</b>	designation of a person who is transitioning from female to male (Female to Male)
<b>GAHT</b>	Gender Affirming Hormonal Treatment (Gender Affirming Hormonal Treatment)
<b>GNRH</b>	Gonadotropin-releasing hormone (Gonadotropin-Releasing Hormone)
<b>Hb</b>	Haemoglobin
<b>HDL</b>	High-Density Lipoprotein (HDL)
<b>HPV</b>	human papillomavirus (Human Papillomavirus)
<b>Ht</b>	hematocrit
<b>i. m.</b>	intramuscular
<b>ICD</b>	International Classification Of Diseases
<b>ICD -11</b>	11th Revision of the International Classification Of Diseases

<b>INAH -3</b>	Interstitial Nucleus of the Anterior Hypothalamus (Interstitial Nucleus of the Anterior Hypothalamus)
<b>K</b>	Potassium
<b>L DL</b>	Low-Density Lipoprotein (LDL)
<b>L H</b>	luteinizing hormone
<b>MKCH</b>	International Classification of Diseases
<b>MKCH -10</b>	10th revision of the International Classification of Diseases
<b>MMPI -2</b>	Minnesota Multiphasic Personality Inventory ®-2
<b>MtF</b>	the designation of a person who is going through a male-to-female transition (Male to Female)
<b>At</b>	Sodium
<b>UNITED NATIONS</b>	United Nations
<b>P</b>	phosphorus
<b>p. o.</b>	Oral
<b>PRL</b>	Prolactin
<b>RL T/RL E</b>	Real Life Test/Real Life in the role of the desired gender Experience)
<b>s. c.</b>	Subcutaneous
<b>SHBG</b>	Sex Hormone Binding Globulin
<b>susp.</b>	suspicious (raising suspicion of a disease/condition)
<b>t. d.</b>	transdermal
<b>TAG</b>	triacylglycerols
<b>TST</b>	testosterone
<b>UPT</b>	abortion
<b>VL D</b>	general practitioner for adults
<b>VL DD</b>	general practitioner for children and adolescents
<b>WHO</b>	World Health Organization
<b>WMA</b>	World Medical Association
<b>WPATH</b>	World Professional Association for Transgender Health

### **Definition of basic terms**

**Transsexualism:** is a diagnostic category in ICD-10, F64.0, characterized by a desire to live and be accepted as a member of a sex other than that assigned to the individual at birth, usually accompanied by a sense of discomfort with one's own anatomical sex or its inadequacy, and a desire for hormonal and surgical treatment that would align the individual's body with the desired/preferred sex.

**Transition:** is the complex and usually gradual process of matching a person's gender expression and behaviour, as well as his/her primary and secondary sex characteristics, in order to come as close as possible to the desired/preferred gender and to conform to it overall. In this complex process, a distinction can be made between social, medically mediated (i.e. hormonal, surgical, etc.) and legal transitions, in which an administrative transcription of the

sex is made at the registry office, which

Slovak legislation refers to it as "gender reassignment".

- **Male to female (MtF):** used to refer to a person who is transitioning the transition from male to female.
- **Female to male (FtM):** used to refer to a person who is transitioning from female to male.

**Transgender person:** is a gender non-conforming person, or a person whose gender identity transcends the gender binary, i.e. the established, conventional or stereotypically perceived categories of masculinity and femininity in our culture and historical period. Conceptually, it is a much broader concept than transsexualism.

**Hormonal treatment:** is treatment with hormonally active substances to modify physical characteristics in accordance with the desired/preferred sex.

**Surgical treatments:** are surgical interventions for the purpose of altering primary and/or secondary sex characteristics in accordance with the desired/preferred sex.

**Psychotherapy:** are psychotherapeutic interventions focused on the individual needs of the adult with transsexualism.

**Real Life Test / Real Life Experience , RL T/RL E:** is the period in the life of a person with transsexualism during which he/she begins to live in the role of the desired/preferred gender (social transition).

## **Competencies**

### **Obligatory:**

**Doctor with specialisation in psychiatry (psychiatrist):** diagnosis, development of an individual diagnostic plan, development of an individual treatment plan, monitoring of the condition, complex management of diagnosis and health care, treatment of psychiatric comorbidities, indication of surgical operations, provision of psychotherapy, information on reproductive options, coordination of a multidisciplinary team of professionals who participate in the complex management of health care persons with suspected or diagnosed transsexualism.

**Doctor with specialisation in psychiatry (psychiatrist) with 5 years of experience, psychiatrist with specialisation in psychiatric sexology (psychiatrist - sexologist), psychiatrist with specialisation in sexology (psychiatrist - sexologist):** diagnosis, development of individual diagnostic plan, development of individual treatment plan, monitoring of condition, complex management of diagnosis and health care, treatment of psychiatric comorbidities, indication of surgical treatment, treatment of psychiatric comorbidities, treatment of psychiatric comorbidities, treatment of psychiatric comorbidities, treatment of psychiatric comorbidities, treatment of psychiatric comorbidities, treatment of psychiatric comorbidities, treatment of psychiatric comorbidities, treatment of psychiatric comorbidities, treatment of psychiatric comorbidities, treatment of psychiatric comorbidities, treatment of psychiatric comorbidities, surgical procedures, the provision of psychotherapy, the issuance of a medical opinion to change sex, information about reproductive options, coordination of a multidisciplinary team of specialists who participate in the complex management of health care of an adult with suspected or confirmed dg. F64.0.

**Doctor with specialization in endocrinology (endocrinologist):** diagnosis and differential

diagnosis of other endocrinopathies and comorbidities, assessment of the appropriateness of hormone therapy, management of hormone therapy.

**Doctor with specialisation in gynaecology and obstetrics (gynaecologist-obstetrician), gynaecologist-obstetrician with specialisation in gynaecological sexology (gynaecologist-obstetrician-sexologist), gynaecologist-obstetrician with specialisation in sexology (gynaecologist-obstetrician-sexologist), gynaecologist-obstetrician with specialisation in reproductive medicine:** diagnostics

and differential diagnosis of other gynaecological diseases, surgical treatment, prevention and regular monitoring of the condition, management of follow-up hormone treatment, information on reproductive options, contraception and prevention of sexually transmitted infections.

**Doctor with specialization in urology (urologist), urologist with specialization in sexology (urologist-sexologist):** diagnosis and differential diagnosis of other urological diseases, surgical treatment, prevention and regular monitoring of the condition, management of follow-up hormonal treatment, information on reproductive options and prevention of sexually transmitted infections.

**Psychologist with specialization in clinical psychology (clinical psychologist):** psychodiagnostics, comprehensive clinical psychological examination, differential diagnosis, provision of supportive psychotherapeutic interventions aimed at to support coping strategies in the context of new life circumstances.

**Doctor with specialisation in surgery (surgeon), doctor with specialisation in plastic surgery (plastic surgeon):** surgical interventions and post-operative care.

**Doctor with a specialization in medical genetics (geneticist):** examination of karyotype and other genetic abnormalities.

**Doctor with specialisation in general medicine (adult general practitioner, VL D):** primary health care and interaction with other specialists involved in the complex health care management of an adult with suspected or confirmed dg. F64.0 .

**Doctor with specialisation in paediatrics (paediatrician, VL DD):** primary health care and liaison with other specialists involved in the complex health care management of an adult with a suspected or confirmed dg. F64.0, if she is in his care after the age of 18.

**Nurse:** nursing care.



**Optional:**

**Doctor in specialty training in the specialty of psychiatry:** during inpatient treatment of a person with suspected or confirmed dg. F64.0 under the supervision of a psychiatrist carries out diagnosis, monitoring of the condition, treatment of psychiatric comorbidities.

**Doctor with specialization in internal medicine (internist):**

differential diagnosis and treatment of associated diseases and their relationship to treatment.

**Doctor with specialization in dermatovenerology (dermatovenerologist):** differential diagnosis and treatment of associated diseases and their relationship to treatment, prevention and management of selected sexually transmitted infections, cosmetic corrective dermatology.

**Doctor with a specialisation in otorhinolaryngology (otorhinolaryngologist):**

operative treatment in connection with a change in physical characteristics.

**Doctor with specialisation in phoniatri (phoniatriest):** voice therapy.


**Psychologist, clinical psychologist:** supportive psychotherapeutic interventions aimed at promoting coping strategies in the context of new life circumstances.

**Specialist (psychologist, clinical psychologist, physician) with certified professional activity psychotherapy (psychotherapist):** supportive psychotherapeutic interventions aimed at promoting coping strategies in the context of new life conditions, psychotherapy.

**Therapeutic educator:** psychoeducation and psychosocial rehabilitation in case of indication of additional treatment.

**Social worker:** dealing with social issues.

**Table 1:** Involvement of multidisciplinary team members in the diagnostic, intervention and follow-up phases of comprehensive health management of transsexualism

 <b>Involvement of multidisciplinary team members in the diagnostic, intervention and follow-up phase of comprehensive health management of transsexualism</b>			
Specialist participating in the health management of a person with F64.0	Comprehensive health management phase		
	Diagnostic	Intervention	Follow-up
Psychiatrist	+	+	+/-
Psychiatrist with 5 years of experience, sexologist	+	+	+/-
Gynaecologist-obstetrician, gynaecologist-obstetrician-specialist in reproductive medicine, gynaecologist-obstetrician-sexologist	+	+	+
Urologist, urologist - sexologist	+	+	+
Endocrinologist	+	+	+
Doctor in specialisation training in the specialisation of psychiatry	+/-	+/-	+/-
Clinical Psychologist	+	+/-	+/-
Psychologist	-	+/-	+/-
Psychotherapist	+/-	+/-	+/-
Social worker	-	+/-	+/-
Geneticist	+	-	-
VLD, VLDD	+	+	+
Surgeon, plastic surgeon	-	+/-	+/-
Therapeutic Educator	-	+/-	+/-
Dermatovenerologist	-	+/-	+/-
Otorhinolaryngologist (phoniatriest)	-	+/-	+/-
Internist	-	+/-	+/-
Sister	+	+	+

- + mandatory presence of a member of the multidisciplinary team in the phase of comprehensive medical management of transsexualism
- the absence of a member of the multidisciplinary team in the phase of comprehensive medical management of transsexualism
- +/- optional presence of a member of the multidisciplinary team in the phase of comprehensive health management of transsexualism

## Home

The purpose of the standard procedure developed is to establish a uniform procedure for the diagnosis and comprehensive management of health care for an adult with transsexualism (dg. F64.0). It has been developed on the basis of adaptation of international procedures for this diagnostic category, which are developed on the basis of interdisciplinary expert consensus, i.e. Delphi process, consensus opinions of expert groups of foreign professional societies - Czech Republic, Germany, Austria, USA, Great Britain and WPATH (1-6). Ensuring access to health care for these persons is in accordance with the Constitution of

the Slovak Republic, the UN Convention

on the rights of persons with disabilities, as well as the case law of the European Court of Human Rights (ECtHR) (7-9). The World Medical Association (WMA) emphasises the right of people to self-determination about their gender, which should be respected and accepted in a non-discriminatory manner by professionals, government and state organisations (10). People with dg. F64.0 should have stable access to comprehensive health care that supports gender reassignment (11). Recommendations for medical management set minimum time criteria but are not intended to have predefined maximum time criteria, as it is important to respect the patient's preferred time course to allow for gradual adaptation to the new living situation. The aspects of informed consent and participatory decision-making, based on congruence in the patient-physician relationship, should play an essential role in the indication of individual procedures (2).

Important factors are transparency in the diagnostic process and health management, and within these, enabling a differentiated and individualised approach. The common goal of diagnosis and comprehensive health care management of an adult with dg. F64.0 is to alleviate the suffering that may be associated with this diagnosis, to improve quality of life and to achieve a satisfactory integration into society. Treatment aimed at changing gender identity in the sense of matching with the sex assigned at birth or genetic sex is not effective and is currently considered unethical (1). This statement is supported by the Slovak Psychiatric Society, which distances itself from any efforts to influence the sexual orientation and gender identity of individuals with gender insecurity in the sense of correction, conversion or externally induced change. From a professional point of view, gender identity is regarded as unchangeable by external interventions (12).

Health care for an adult with dg. F64.0 is provided by a multidisciplinary team of specialists. It is to promote a non-moralizing, non-stigmatizing, non-discriminating and non-pathologizing approach to people with dg. F64.0 by health professionals and the public (4, 6).

The priority goal of the standard procedure is to define the pathway of an adult with dg. F64.0 across interprofessional healthcare. The standard procedure does not include surgical procedures for specific surgical procedures, as several of these are not currently performed in the country.

## **Prevention**

**Primary prevention:** as transsexualism has no known aetiology, primary prevention is unknown.

**Secondary prevention:** includes access to comprehensive health care, early diagnosis, adequate comprehensive health care management, awareness-raising activities and a non-moralizing, non-stigmatizing, non-discriminatory and non-pathologizing approach to people with dg. F64.0 by health professionals and the public.

**Tertiary prevention:** includes follow-up health care according to the individual requirements of the person with dg. F64.0.

## **Epidemiology**

No epidemiological survey of the incidence and prevalence of transgenderism or transsexualism in the general population has yet been conducted in Slovakia (13). Information from the literature and experience from around the world suggests that increasing numbers of transgender individuals are seeking the care of psychiatrists or psychologists, or clinics dealing with

transgenderism (14, 15). The 1994 DSM-IV reports a prevalence of gender dysphoria in adulthood of 1:30,000 for individuals with male sex assigned at birth (natal male) and 1:100,000 for individuals with female sex assigned at birth (natal female) (16). Its fifth revision in 2013 (DSM-5) already reports a higher prevalence, with 0.005-0.014% for individuals assigned male sex at birth and 0.002-0.003% for those assigned female sex at birth (17). The ratio of natal males to females seeking care from specialist clinics is reported by the DSM-5 to be in favour of the male sex assigned at birth, with ratios of 1.1:1 - 6.1:1, except in Japan (1:2.2) and Poland (1:3.4), where the

Epidemiological data are available on the higher proportion of natal women seeking psychiatric-psychological help (17). In Central European countries, for example, individuals with FtM were until recently predominantly transgender, in contrast to Western Europe (18). The reported ratio of MtF to FtM transgenderism is gradually changing in the world literature in terms of

a reduction in the previous prevalence of MtF, although it is safe to say that the prevalence of MtF mismatch is still consistently higher (15). According to a meta-analysis of 21 studies, the prevalence of transsexualism in natal men is 1:14,705 and natal women is 1:38,461, with an observed meta-analytic prevalence of 4.6 individuals per 100,000 population (14), although there are also studies from regions that indicate a significantly higher prevalence. For example, an American study published in 2017 found a 0.53% prevalence of transgenderism among American adults (19), and a Spanish study from the same year found a prevalence of 22.1 per 100,000 inhabitants in Madrid (20). Estimates of prevalence vary from study to study, but collectively indicate an increasing prevalence of transgenderism and transsexualism (13).

## **Pathophysiology**

Genetic, hormonal and other biological factors are primarily involved in the emergence and development of gender identity, or the subjective sense of belonging to a particular sex, although environmental factors also have an impact (21). Pathophysiological research involving transsexualism has focused more broadly than on persons diagnosed with F64.0, i.e., transgender persons who are gender nonconforming and whose gender identity transcends the gender binary in the categories of masculinity and femininity. Transgender persons differ from nontransgender persons in the volume of subcortical brain regions and in superficial regions, but not in cortical thickness (22), thus they have a different brain phenotype. They differ from gender congruent individuals, for example

in the neural networks that mediate the cerebral representation of one's own body schema. Differences can be found in the pregenual anterior cingulate cortex, the temporo-parietal junction, and the area fusiformis, respectively, and transgender persons appear to have lower structural and functional connectivity between the anterior cingulate and the precuneus and in the right occipito-parietal cortex (23). As the neuroanatomical differentiations of transgender individuals extend beyond neuronal circuits relevant to sexual or endocrine function, it can be concluded that transgenderism is also conditioned by neuronal networks important for self-

perception (24). Thus, gender-differentiated self-perception is conditioned in transsexualism

neurobiologically, and it is by no means an arbitrary human decision, but rather a deep and complex self-identity. Past attention of researchers has also focused on the sexually dimorphic nucleus nucleus interstitialis striae terminalis (BNSTc), which belongs to the septal nuclei, and on the third interstitial nucleus of the anterior hypothalamus (INAH-3). In males, the BNSTc is twice as large and has twice the number of somatostatin-expressing neurons as in females. INAH3 is 1.9-fold larger and has 2.3-fold more neurons in males than in females. MtF transgender individuals have INAH-3 and BNSTc earlier than natal women, whereas FtM transgender individuals have characteristics similar to natal men (25-27). These neuroanatomical differentials arose developmentally and point to prenatal masculinization or feminization of the brain, which is unaffected by circulating sex hormone levels in adulthood (25).

## Classification

The diagnosis of transsexualism is made according to the current revision of ICD-10, which provides the following diagnostic criteria for the category F64.0:

- A. The desire to live and be accepted as a member of the opposite sex, usually accompanied by a sense of discomfort with one's own anatomical sex or its inadequacy, and a desire for surgical and hormonal treatment to bring the patient's body into alignment with the preferred sex.
- B. Transsexual identity lasts at least 2 years.
- C. Transsexualism is not a symptom of another mental disorder, such as schizophrenia, nor is it associated with a chromosomal abnormality (28).

The diagnosis of transsexualism has been changing terminologically and conceptually over the past decade. Recent revisions of disease classifications have replaced the diagnostic category of transsexualism with others, which should contribute to the depathologization and destigmatization of the issue. The DSM-5 classification of mental disorders used in the USA (17), as well as its revised version (29), allocate this diagnostic category to a separate chapter, which they refer to as 'Gender Dysphoria'. It is defined as a marked discrepancy between internally experienced and assigned gender, lasting at least six months. In 2018, the 11th revision of the ICD, approved by the WHO but not yet implemented by the Slovak Republic, lists the diagnostic category "Gender Incongruence" (30). It is characterised as an apparent and persistent discrepancy between an individual's internally experienced gender and his or her assigned sex, and the experience of gender incongruence must be continuously present in adults for at least several months. Thus, both recent revisions of the classification systems show significant changes regarding transsexualism. However, the diagnostic criteria remain unchanged in substance. The symptomatic (A) and exclusion (C) criteria remain respected; the progressive temporal criterion (B) is relaxed. Importantly for the application of this standard, the new revisions to the classifications, despite their timeliness, do not introduce biological diagnostic criteria that would need to be considered in the recommended procedures and would have a potential impact on the recommended comprehensive medical management of a person with transsexualism. As significant in terms of destigmatizing persons with gender nonconformity, it should be seen that diagnostic the category of gender non-conformity no longer appears in the chapter among psychiatric disorders, but is listed in a separate chapter in ICD-11 "Conditions related to sexual health"

("Conditions Related to Sexual Health"). Despite the above, after the implementation of ICD-11, the authors set themselves the task of revising the standard.

## **Clinical picture**

The basic manifestation of transsexualism is an individual's desire to live and be accepted as a member of a gender other than the one determined at birth (gender non-conformity). This feeling is usually accompanied by a sense of dissatisfaction and discomfort stemming from the sex assigned at birth (gender dysphoria). Accordingly, the person with transsexualism also acts, or tends to act. It usually manifests itself in childhood and persists throughout life. It can manifest itself in the way of dressing, modification of appearance, preference for toys and games in preschool. The clinical picture meets the diagnostic criteria of ICD-10. Other psychopathological symptoms may not be present.

## **Comprehensive medical management of transsexualism**

Comprehensive medical management of transsexualism has three phases: diagnostic, intervention and follow-up. The duration of each phase has no maximum time limit, depending on the individual needs of the person undergoing them. However, the standard defines their minimum length. However, the validity of some examinations and procedures may also be limited and must be repeated if the specified time interval is exceeded.

Recommendations for this diagnostic category have been developed by adapting international practices developed through interdisciplinary expert consensus (1-6, 31-36).

### **1. Diagnostic phase:**

It aims to answer the questions:

1. Does the condition meet the diagnostic criteria for dg. F64.0?
2. Is psychiatric comorbidity present? What kind? Does it require treatment? Can it be managed in parallel with the management of dg. F64.0, or should it be treated first?
3. Is somatic comorbidity present? Which one? Does it require treatment? Can it be managed in parallel with the management of dg. F64.0, or should it be treated first?
4. Does a person with dg. F64.0 to begin comprehensive medical management of transsexualism? Is such a procedure medically indicated? Is the person with dg. F64.0 ready to live the rest of his/her life in the role of the desired gender?

**Journey of an adult with susp. dg. F64.0 in the system of comprehensive health care** Adult with suspected dg. F64.0 presents for a psychiatric examination without a recommendation or with a recommendation from the VLD, VLDD, psychologist or clinical psychologist after a clinical psychological examination (Diagram 1).

### **1. Psychiatric examination with a focus on the diagnostic criteria F64.0 and possible other concomitant psychopathology.**

The psychiatric examination includes a detailed sexological history. It focuses in particular on psychosexual development, pre-pubertal gender non-conformity, the course of puberty and adolescence, gender identity, its experience and manifestations, retrospectively their consistency and stability over time,



partnerships, terms used by the person to describe their person/gender, coming out, acceptance by the environment, experiences of stigma and discrimination, manifestations of gender dysphoria and attempts to alleviate it.

After the first psychiatric examination, the creation of an individual course of further medical care begins .

**Ongoing psychiatric check-ups are recommended at least 4 times during one year, or more frequently according to the individual needs of the person with suspected dg. F64.0.** They focus on prospective ongoing monitoring and assessment of survival and manifestations of gender identity, their consistency and stability over time, gender self-expression, manifestations of gender dysphoria and attempts its mitigation, psychosocial adaptation, assessment of functioning in personal and professional life, subjective assessment of acceptance by the environment, monitoring the dynamics of acceptance of role change. Any associated psychopathology is assessed.

Readiness and adaptation to role change is prospectively monitored clinically. If a person is undergoing RLT/RLE and changes in appearance are occurring, at the person's request, at any time during the diagnostic/intervention phase, a statement may be issued stating that the person's appearance may differ from the gender data due to the diagnosed condition and ongoing treatment and/or the name on his/her documents (which facilitates communication with the authorities) (Annex 1).

## **2. Differential diagnosis of psychiatric comorbidities**

In the differential diagnosis of other psychiatric disorders, they should be approached in such a way that there may be a secondary diagnosis (comorbidity) that does not preclude F64.0 but accompanies it. In the case of a psychotic disorder, it should be treated first and only after the psychotic disorder is in remission should the diagnosis of F64.0 be pursued. Other comorbid psychiatric disorders should be treated in parallel until remission is achieved and, if remission cannot be achieved, at least until a stable state is reached. Only in this state should therapeutic interventions that lead to physical changes be recommended (2). Diagnosis and treatment of comorbid psychiatric disorders should be based on the relevant SDTP. The alleviation of psychiatric disorders that are causally related to dg. F64.0 (gender dysphoria in the DSM-5) can be achieved by initiating the process of transition.

In the course of psychiatric follow-up and possible treatment of psychiatric comorbidities, it is necessary to continuously reassess the individual course of further medical care while maintaining the condition of concordance in the therapeutic doctor-patient relationship. The person with suspected dg. F64.0 should be presented with diagnostic and medical management options to the extent that they enable him/her to make informed decisions. The diagnostic process and its duration (including the possible need for prolongation) are influenced by ongoing professional findings. Particular attention should be paid to suicidal risk, which is higher than in the general population, at all stages of health management (43-44).

Informing the person about the recommended diagnostic procedure indicated to determine dg. F64.0 should be confirmed by signing an informed consent to the individual

diagnostic plan.

### **3. Other obligatory diagnostic examinations:**

**a. clinical-psychological diagnostic examination:** psychiatrist/psychiatrist-sexologist recommends a person with suspected dg. F64.0 to undergo a psychodiagnostic examination (if not performed before the psychiatric examination). Its aim is to assess the extent to which the person identifies with the desired gender, to rule out hidden psychopathology and to confirm the diagnosis of transsexualism psychological methods.

The examination includes:

**Medical history:** as in the usual clinical-psychological examination, with emphasis on childhood and adolescence and gender identity (gender-specific behavioural manifestations are assessed). If the patient consents, a similarly focused heteroanamnesis.

#### **Sexual history:**

Sexual maturation: menstruation, copulation, etc.

Probatum sexual activities: age at first masturbation and accompanying fantasies, current masturbation fantasies, first love, orientation, first date, first kissing, first necking, first **petting**, first coitus - time interval between first and second coitus, sexual appetite, real frequency of sex. Contact frequency, preference for objects of sexual interest (female, male, other), sexually arousing stimuli (body parts of the preferred person), erotic dreams and daydreams, current sex and partner life, attitude of family members to **gender incongruence**, expressions to describe one's person, coming out, possible attempts to **alleviate gender dysphoria**, **stability of gender incongruence** (time course), subjective assessment of the acceptance of gender role change by the environment and one's own comfort in the desired role, assessment of the consistency of the decision in relation to the personality structure, etc.

#### **Obligatory psychological diagnosis and differential diagnosis:**

Intellect, indicative determination of intellectual level.

Personality, assessment of personality maturity, self-regulatory mechanisms, emotion stability, frustration tolerance, coping mechanisms, defense mechanisms, interpersonal aspects, adaptability.

Sexuality, psychosexual development, psychosexual maturity, sexual identification, sexual orientation, sexual preference, sexual role, sexual behaviour.

#### **Recommended methods:**

Clinical methods: focused interview, observation. Test methods:

- intelligence tests to rule out mental retardation in indicated cases,
- questionnaire methods - MMPI-2 and other personality tests with diff. dg. potential,
- Projective techniques - Rorschach method, Human Figure Drawing Test, or other projective techniques,
- Selection more methods by individual experience psychologist with psychodiagnostic methods depending on the specific case.

**Conclusion of the clinical-psychological diagnostic examination:** should include a description of the personality, the degree of identification with the desired/preferred gender identity, the degree of readiness for the transition process, the ability to adequately cooperate in the intervention phase (including the indication of irreversible surgical operations from a psychological point of view), or contraindications to the initiation of this process. In indicated cases, it should also include a recommendation for psychological intervention.

**Number of examinations:** the clinical-psychological diagnostic examination is usually carried out in two sessions. After one year, a follow-up psychological examination is carried out, which focuses on the dynamics and stability of gender incongruence and on the current psychological state. If there is a diagnostic need, psychological examinations may be repeated, possibly over a longer period of time.

**Psychotherapy : is not** a prerequisite for diagnosis nor a mandatory component of medical management of transsexualism. It is indicated when necessary and focuses on the patient's individual problems (usually short-term psychotherapy or specific psychotherapeutic interventions to alleviate superimposed psychopathological symptoms). In individual cases, taking into account the person's needs and in agreement with the person, psychotherapy may be recommended as it may be beneficial for further health management and decisions.

Supportive psychotherapy (selection of the approach according to the individual needs of the patient and the practice of the workplace) usually focuses on:

- promoting self-acceptance,
- promoting self-esteem,
- supporting the development of identity,
- Coping possible internalized negative attitudes of society towards sexual minorities,
- support the process of coming out,
- Reflection and processing of experiences and conflicts in the role of chosen gender,
- support in coping with family or partner problems,
- support in making decisions about medical treatments,
- support after procedures related to changing body appearance,
- promoting coping strategies in the context of new living conditions.

**b. Genetic testing with a focus on karyotype** is recommended by a psychiatrist/psychiatrist/sexologist if not already performed prior to the psychiatric examination. The results of the genetic testing should be made available to the entire multidisciplinary team for consideration of their impact on the future course of care.

**c. gynaecological or urological examination**

In the diagnostic phase, the psychiatrist/psychiatrist-sexologist recommends the person with suspected dg. F64.0 gynaecological or urological examination according to the sex assigned at birth.

Recommendations for health care by gynaecologist-obstetrician or gynaecologist-obstetrician-sexologist for persons with dg. F64.0 are an adaptation of recommendations from The American College of Obstetricians and Gynecologists ( 31) and several recent publications addressing the current status of health care for transsexualism (1-6, 32).

The gynaecology and urology outpatient clinics should be open/friendly and welcoming to all persons in need of gynaecological, obstetric and urological care. The gynaecologist/obstetrician/urologist should be regularly trained and have basic knowledge also in the care of people with dg. F64.0. Already at the first encounter, a "gender neutral" environment is important to establish adequate trust and an honest open conversation. For a person with dg. F64.0 may be uncomfortable with gynaecological examinations, so an individualised approach is important, as is thorough information about the current examinations and their significance.

The main roles of the gynecologist-obstetrician and urologist in the diagnostic phase of transsexualism include participation in the identification of transsexualism with other members of the multidisciplinary team, exclusion/detection of gynecologic/urologic comorbidities, explanation of the benefits and complications of each option within the context of health care and reproductive options, education, and regular pre-transition follow-up.

The gynaecologist-obstetrician performs a gynaecological examination focused on general anamnestic data, gynaecological history (menarche, menstrual cycle - regularity, deviations, dysmenorrhoea, last menstrual period, gynaecological diseases, contraception, sexually transmitted infections, pregnancies - births, miscarriages, UPT, extrauterine pregnancies, HPV vaccination), a thorough sexual history - including questions about risky sexual behaviour, prevalence of risky sexual intercourse, both preferences and concerns within sexual life. Similarly, the urologist will perform a urological examination focusing on a thorough sexual history, sexually transmitted infections, and identification of possible urological comorbidity. The detection of gynaecological/urological abnormalities (benign, malignant diseases) does not affect the diagnostic

F64.0 phase, but may have an impact on the intervention phase, so the finding should be discussed with other members of the multidisciplinary team. In the process of diagnosing F64.0, other possible causes need to be ruled out, as well as other causes of disordered sexual development (although these are usually diagnosed by adulthood).

The gynaecologist-obstetrician thoroughly informs about reproductive options, about the pitfalls of unwanted pregnancy and the use of appropriate contraception, and from the gynaecological point of view about the possibilities, benefits and pitfalls of hormonal and surgical intervention after confirmation of the diagnosis. F64.0. The urologist informs about reproductive options, the possibilities, benefits and pitfalls of hormonal and surgical intervention after confirmation of dg. F64.0.

Options for fertility preservation of persons with dg. F64.0 are the same as for persons wishing fertility preservation prior to gonadotoxic therapy due to cancer treatment or elective fertility preservation (freezing of oocytes/sperm, embryo, possibly in exceptional cases ovarian/testicular tissue). It is also necessary to provide information on the success

rate of these methods as well as on their financial cost. If they decide

for such a procedure, it is recommended to undergo it before starting hormone therapy. Hormone therapy for transient periods is not effective contraception. Sexually active individuals with preserved gonads should be thoroughly instructed in this fact. In FtM, the occurrence of amenorrhoea does not imply infertility in the case of retained uterus and ovaries. Therefore, adequate

forms of contraception. Conventional hormonal contraception is not a specific contraindication to hormonal therapy, but most people want to avoid taking estrogen, so hormonal intrauterine devices, contraceptive implants, or depot medroxyprogesterone acetate are the most preferred forms.

All persons should be adequately instructed in the prevention of sexually transmitted infections.

#### **d. endocrinological examination**

Health care recommendations by endocrinologists for persons with dg. F64.0 are an adaptation of international recommendations and several recent publications dealing with the current state of health care for transsexualism (33 - 36).

In the diagnostic phase, the psychiatrist/psychiatrist-sexologist recommends to the person with suspected dg. F64.0, an endocrinological examination that focuses on:

- 1) confirmation of the diagnosis by clinical examination, history and laboratory analyses (PRL, FSH, LH, E2, TST, SHBG, DHEA-S, cortisol), and if necessary some imaging tests,
- 2) diagnosis and treatment of potential concomitant endocrinopathy until the condition stabilises,
- 3) assessment of the suitability of a person with dg. F64.0 to the planned endocrinological treatments on the basis of personal and family history, evaluation of the impact of other long-term medications, initial physical examination, pulse and blood pressure measurement, basic laboratory analyses (glycemia, renal function, hepatic and lipid profiles, Na, K, Ca, P, red blood cell count, platelets), assessment of risk factors, including abusive and unhealthy lifestyles, obesity, eating disorders, etc.

#### **4. psychiatric examination**

Diagnostic, differential diagnostic examinations and possible treatment of comorbidities are carried out in parallel in the diagnostic phase in a multidisciplinary team (Table 1), coordinated by a psychiatrist/psychiatrist-sexologist. The examinations are aimed at differential diagnosis of pathological conditions and assessment of the appropriateness of further medical care provided to persons with dg. F64.0. For clarity and better orientation in the indicated

and examinations completed during the diagnostic phase, it is recommended that the data be recorded in the Adult Diagnosis Process Protocol for F64.0, which is part of the person's medical records (Annex 2).

After assessment of the ICD-10 diagnostic criteria for category F64.0, completion of all the above examinations, stabilization of any comorbidities, the psychiatrist determines dg. F64.0 and informs the person with transsexualism about the possibilities of further medical care. At the same time, he/she will instruct the person about medical and non-medical risks, about the need to properly and consistently follow the doctor's recommendations, about the possibility of changing the name to a neutral one and, together with the person with dg.

F64.0 draws up a definitive individual treatment plan, including signing an informed consent.

## **II. Intervention phase**

The aim of the intervention phase is to enable the person with dg. F64.0 to live with the desired/preferred gender identity and to adjust to the new role in order to achieve the highest possible quality of life and satisfactory integration into society.

In the intervention phase after the diagnosis is completed, it can provide:

Psychiatric, psychological, psychotherapeutic and psychosocial care to be indicated according to the individual needs of the person with dg. F64.0.

RLT/RLE in the role of desired/preferred gender is not a mandatory part of the diagnostic or intervention phase of the medical management of transsexualism. However, in individual cases, taking into account the person's needs and in agreement with the person, they may be recommended as they may be beneficial for further health management and decisions.

Somatic health care of adults with dg. F64.0:

- A. **PARTIAL REVERSE PROCEDURES** : endocrinological interventions - hormone therapy indicated separately.
- B. **IRREVERSIBLE PROCEDURES** : surgical operative procedures:
  - surgical interventions resulting in permanent loss of sex hormone production; and reproductive capacity, should be indicated at least 1 year after the start of hormone therapy,
  - aesthetic surgical interventions aimed at adapting body characteristics (mammoplasty, phonosurgery),
  - reconstructive surgical interventions aimed at the creation of the genitalia.

## **ENDOCRINOLOGICAL INTERVENTIONS**

They are carried out on the basis of a written recommendation of a psychiatrist or psychiatrist-sexologist with whom the person with dg. F64.0 has signed an individual treatment plan, which includes the indication of endocrinological interventions. This recommendation must not be older than 1 year. Treatment is started only after the person has been thoroughly informed about the treatment, its duration and risks and has subsequently signed an informed consent.

**The aim of endocrinological management of adults with dg. F64.0, which was developed by adapting international practices (33-36), is to safely and effectively develop physical characteristics that confirm their gender self-identification:**

- 1) by suppressing the production/secretion of endogenous sex hormones at birth of the assigned sex,
- 2) achieving and maintaining levels of administered exogenous sex hormones consistent with the sex/gender experienced, within their physiological range for adult healthy individuals of the sex assigned to them at birth.



**The role of the endocrinologist in the management of health care delivery to adults with dg. F64.0:**

- 1) establishing an endocrinology management plan, discussing and considering the need for available medical procedures to possibly preserve fertility before starting hormone treatment (see in section 3.c),
- 2) initiation and monitoring of hormone therapy, its possible side effects,
- 3) long-term, often lifelong monitoring and treatment of people with dg. F64.0 especially after surgical operation - gonadectomy,
- 4) at any time during follow-up, cooperation with a psychiatrist/psychiatrist/sexologist who manages an adult with both suspected and confirmed dg. F64.0 and with other professionals involved in the management of health care as appropriate. Ongoing communication of the progress of the endocrinological intervention also to the VLD and VLDD if they are providing health care to the adult.

#### **A. GAHT in AFAB, FtM**

Absolute contraindications to this type of hormonal therapy are pregnancy, relative are severe hypertension, sleep apnea syndrome and polycythemia.

#### Adverse effects :

- cessation of menstruation: usually occurs spontaneously with testosterone treatment within a few months of starting it,
- if this does not happen, temporary treatment with gestagens, endometrial ablation, treatment with GnRH analogues (not available in Slovakia) is possible,
- virilization: occurs on average in 1-3 months, with a peak in 6-9 months and establishment within 2 years: Change in weight, decrease in body fat ratio and increase in muscle mass ratio, deepening of voice, change in facial and body hair to male appearance, androgenic alopecia, increase in acne tendency, clitoromegaly, decrease in vaginal lining, endometrial atrophy, decrease in mammary gland volume, increase in sexual appetite, cessation of menstrual bleeding,
- impact on mental health: reduced experience of stress, reduced anxiety, increased self-esteem and self-acceptance.

Side effects and risk factors: increase in systolic blood pressure, erythrocytosis, increase in hemoglobin and hematocrit, sleep apnea syndrome, congestive heart failure, headache, irritability, edema. Increased risk of cardiovascular and cerebrovascular sudden events, breast cancer and bladder cancer has not been demonstrated in meta-analyses of medium-term follow-up; long-term follow-up is needed. Bone density decreases only after omitting testosterone therapy (it is converted by aromatase in the bones to effective estradiol) and after undergoing gonadectomy.



## B. GAHT in AMAB, MtF


The absolute contraindication to this type of hormone therapy is unknown, relative contraindications are obesity and smoking.

### Adverse effects :

- suppression of the expression of male secondary sex characteristics by suppressing the production, secretion or application of endogenous sex hormones,
- feminization: begins to manifest 3 months after the start of treatment, with a maximum at 6-9 months, stabilizing within 2 years: development and maintenance of female secondary sexual characteristics - redistribution of body fat and muscle mass, breast growth, skin refinement, reduction of sebaceous gland activity, reduction of facial and body hair, testicular atrophy, reduction in sperm count and quality, disappearance of spontaneous erection,
- impact on mental health by increasing self-esteem and self-acceptance.


Adverse effects and risk factors: hypertension, thromboembolic disease (increases with age, smoking, addition of gestagens to therapy), K retention with spironolactone therapy, increase in TAG, insulin resistance, increase in weight and body fat percentage, increase in risk of cardiovascular disease (related to age, obesity, hypercholesterolaemia and DM 2. type), hyperprolactinemia, meningiomas with prolonged treatment with cyproterone acetate at higher doses, increased risk of breast cancer, prostate cancer (more likely due to psychological barriers to undergoing regular preventive check-ups), hepatotoxicity, cholecystolithiasis, increased risk of fracture (with hypovitaminosis D already before treatment), decrease in bone density (with discontinuation of treatment and after gonadectomy).

**Table 3:** Recommended treatment regimens for MtF

 <b>Recommended treatment regimens for MtF transitions</b>			
<i>Medication group</i>	<i>Drug</i>	<i>Dosage form</i>	<i>dosage</i>
ESTROGENS	Estradiol hemihydrate	p.o.	2 - 6 mg/day
	Estradiol-valerate or cypionate	i.m.	2 - 10 mg/week or 5 - 30 mg / 2 weeks
	Estradiol, patch	ld.	0.025 - 0.2 mg/day
ANTIANDROGEN - PROGESTIN	Cyproterone acetate	p.o.	25 - 50 mg/day
ANTIANDROGEN - STEROID	Spironolactone	p.o.	100 - 300 mg/day
5 alpha - REDUCTASE INHIBITOR	Finasteride	p.o.	2.5 - 5 mg/day
GnRH AGONISTA	Leuprolide acetate	s.c.	3.75 mg/30 days
	Triptorelin	s.c.	11.25 mg/90 days
	Goserelin	s.c.	3.6 mg/30 days 10.8 mg/90 days



**Table 4:** Risks associated with GAHT (6, 49)

 <b>Risks associated with GAHT</b> (highlighted are clinically significant)		
Level of risk	Estrogen-based GAHT	Testosterone-based GAHT
Probably increased risk	<b>Venous thromboembolism</b> <b>Infertility</b> Hyperkalemia <sup>S</sup> Hypertriglyceridemia Weight gain, obesity	<b>Polycythemia</b> <b>Infertility</b> Acne Androgenetic alopecia Hypertension Sleep apnoea syndrome Weight gain, obesity Decline in HDL cholesterol and rise in LDL cholesterol
Probably increased risk in the presence of a risk factor	Cardiovascular diseases Cerebrovascular diseases Meningeoma <sup>C</sup> Polyuria/Dehydration <sup>S</sup> Cholelithiasis	Cardiovascular disease Hypertriglyceridaemia
Possible increase in risk	Hypertension Erectile dysfunction	
Possible increase in risk in the presence of a risk factor	Diabetes mellitus type 2 Osteopenia/Osteoporosis Hyperprolactinemia	Diabetes mellitus type 2 Cardiovascular disease
No risk identified, ambiguous risk	Breast cancer Prostate cancer	Osteopenia / Osteoporosis Carcinoma of the breast, cervix, ovary, uterus, breast

<sup>C</sup> - in combination with cyproterone acetate

<sup>S</sup> - in combination with spironolactone

According to the European Network for the Investigation of Gender Incongruence (ENIGI) multicentre mid-term study (48):

- PRL increase can be induced by estrogen, and its slight increase can be caused by cyproterone acetate in trans AMAB subjects, in which case it decreased after its discontinuation,
- Erythrocytosis was the most common side effect with testosterone treatment in trans AFAB subjects, especially during the first three months. There was a higher risk with the use of testosterone esters than with testosterone undecanoate,
- the level of risk of liver damage was very low, usually only during the first year of GAHT; for renal function, GAHT caused no risk,

- Regarding the lipid profile: in trans AFAB subjects, GAHT with testosterone led to an increase in total cholesterol, LDL cholesterol, and triglycerides, but a decrease in HDL cholesterol, fibroblast factor 21, and adiponectin. GAHT in trans AMAB subjects led to a decrease in HDL cholesterol, but also to a decrease in total cholesterol, LDL cholesterol and triglycerides, to an increase in fibroblast growth factor 2, to a decrease in resistin,
- GAHT in trans AMAB subjects led to both a reduction in insulin sensitivity and a reduction in incretin response to oral glucose load, whereas testosterone treatment in trans AFAB subjects had a positive effect on insulin sensitivity,
- Feminizing treatment in trans AMAB subjects led to procoagulant changes with an increase in factors IX and XI and a decrease in protein C levels,
- All included studies emphasize that a healthy lifestyle has a significant impact on the development of the aforementioned markers of potential cardiovascular risk and venous thromboembolism. The data collected so far are generally limited; longitudinal studies are needed to investigate them,
- Regarding bone density - an increased prevalence of osteoporosis was found in trans AMAB individuals prior to GAHT initiation than in cis men of the general population, probably due to hypovitaminosis D and a less active lifestyle. Trans AFAB individuals had the same bone density as cis women of the general population; initiation of GAHT resulted in increased bone density in both groups at the lumbar spine and femoral neck.

The literature acknowledges the possibility of later diagnosis of cancer in general, and thus higher cancer incidence and shorter survival in transgender people because of their barriers to seeking early health care. Similar reasons often seem to account for late seeking of health care in other serious cases of threats to their health and life.

Antiandrogen GAHT in trans AMAB individuals reduces the risk of prostate cancer but does not completely eliminate it.

In older trans AMAB individuals (in some recommendations over 40 years, others over 45 years) and those at risk (smoking, obesity, sedentary lifestyle), the patch drug form of estrogen GAHT has been shown to be safe with respect to the potential risk of deep vein thrombosis.

Prior to elective surgery, it is recommended to discontinue GAHT 7-21 days before surgery and reinstate 3-7 days after surgery.

For the prevention of deep vein thrombosis and venous thromboembolism, the recommendations included in the NTP "Deep vein thrombosis" apply.

The estimated financial cost of GAHT in transgender people is comparable to the cost of hormone replacement therapy for other indications (hypogonadism, DSD - Disorders of Sex Development).

The choice of medicines is generally dependent on their regional availability and price.


## **SURGICAL SURGICAL INTERVENTIONS**

Surgical procedures performed within the framework of health care for **dg. F64.0** are irreversible. They are carried out on the basis of a written recommendation of a psychiatrist or psychiatrist-sexologist with whom the person with **dg. F64.0** has signed an individual treatment plan, which includes an indication for surgery. This recommendation must not be older than 1 year. Surgical procedures shall only be undertaken after the person has been thoroughly informed and has made an unambiguous decision. **Surgery with removal of the gonads is recommended after a minimum of 1 year of hormone therapy or after individual assessment (Table 3).** Before surgery, the person with **dg. F64.0**, an informed consent for **surgical intervention** should be signed. Thorough medical care before, during and after surgery **and** adequate cooperation of the person with **F64.0** in the treatment are important to achieve the best possible outcome.

Surgical operations are performed in adults with **dg. F64.0** are indicated on the basis of:


- signing of informed consent by a person with **dg. F64.0** to the surgical procedure, which includes instructions on the **nature and consequences** of the surgical procedure, risks, length of hospital stay,
- definitively determined **dg. F64.0** and assessment of the readiness of the person with **dg. F64.0** to live the rest of his/her life in the role of the desired sex by a psychiatrist or psychiatrist-sexologist,
- a referral from a psychiatrist or psychiatrist/sexologist with whom the person with **F64.0** has signed an individual treatment plan (indication for surgery based on a written recommendation),
- psychological examination,
- demonstration of stabilization of health status or remission of comorbidities,
- a minimum of one year of hormone treatment, in the case of a surgical procedure resulting in permanent loss of sex hormone production and reproductive capacity (removal of the gonads).

**Table 5:** Contraindications to surgery for F64.0 (39)

 <b>Contraindications to surgery for F64.0 (39)</b>	
<b>CONTRAINDICATIONS</b>	
ABSOLUTE	RELATIVE
acute phase of psychotic illness	for surgical procedures with removal of gonads is relative contraindication of the impossibility of hormonal treatment for medical reason
somatic contraindication to the surgical procedure (procedure according to the SSTP for individual surgical procedures)	caution is necessary when psychiatric or somatic comorbidities, in general, stabilization of the condition or, if possible, achieving a state of remission of comorbidities is required
disagreement or inability to sign informed consent to surgery	if the patient has not taken hormone therapy for at least 1 year

The individual surgical procedures are divided according to the specialty of gynaecologist-obstetrician, urologist, surgeon and plastic surgeon, and also with regard to the complexity of the operation, whether they can be performed at a regular workplace or whether a specialised workplace specialising in these procedures is required (Table 6).

**Table 6:** Surgical procedures indicated in transit and type of specialised department

 <b>Surgical procedures indicated for transection and type of specialised department</b>		
	<b>Performance</b>	<b>Workplace</b>
FtM	Hysterectomy with/without bilateral salpingoophorectomy	Gynaecology and Obstetrics
	Urethral reconstruction Metoidioplasty Phalloplasty Vaginectomy Scrotoplasty Implantation of erectile and testicular prostheses	Specialised workplace for the above type of operations (i.e. not performed in the Slovak Republic)
	Breast surgery - subcutaneous mastectomy, creation of a male chest	Plastic surgery
MtF	Orchiectomy	Urology
	Penectomy Urethral reconstruction Vaginoplasty	Specialised workplace for the type of operations mentioned (i.e. they are not carried out in the Slovak Republic)



Hysterectomy with/without bilateral salpingo-oophorectomy and orchiectomy are indicated in persons who truly wish and sign an informed consent for this procedure. The choice of surgical procedure should be according to the clinical findings. The removal of the gonads depends on several factors - reproductive plans, the person's own preference, and the final decision should be a joint decision. A specialist in reproductive medicine should also be consulted before the decision to remove the ovaries is made. Whereas, that a number of surgical procedures (Table 6) are currently not performed in Slovakia, it is necessary to put them into practice and in the transitional period to allow people with dg. F64.0 to undergo them abroad in accordance with the procedure set out in the Decree of the Ministry of Health of the Slovak Republic 341/2013 Z. z., dated 23 October 2013, which establishes cross-border healthcare that is subject to the prior authorisation of the relevant health insurer for reimbursement.

### **C. Follow-up healthcare**

Follow-up health care in adults with dg. F64.0 should be available at any stage of health care according to individual needs and taking into account their current life situation (1-6, 31-36). Includes:

#### **Obligatory:**

- ongoing hormone treatment that is long-term and lasts as long as the person needs it. It can be lifelong after surgical intervention with removal of the gonads. Monitoring is required throughout the treatment period as detailed at the intervention phase (by the endocrinologist),
- preventive check-ups (gynaecologist-obstetrician/urologist),
- follow-up after sex reassignment surgery (gynaecologist-obstetrician/urologist, surgeon, plastic surgeon),
- care of the VLD or VLDD (for persons over 18 years of age in the care of the VLDD) .

#### **Optional:** according to individual need

- psychiatric,
- psychological,
- psychotherapeutic,
- psychosocial,
- voice therapy,
- somatic care - including other surgical interventions related to sex reassignment,
- other (e.g. hair therapy, cosmetic and aesthetic care).

#### Follow-up care with an obstetrician/gynaecologist/urologist

Follow-up health care in adults with dg. F64.0 during hormone therapy and/or after surgical intervention includes: regular preventive check-ups and management of any problems that arise. Care of the person with dg. F64.0 who has undergone surgical transition is provided by a specialist according to an individual therapeutic plan.

### FtM preventive monitoring

Screening for cervical cancer should be performed according to age and current recommendations. An individualised approach is necessary. Secondary atrophy due to testosterone makes cervical smear analysis much more difficult and unsatisfactory findings are 10 times more common in FtM subjects than in the general population.

As with the general population of women, FtM with retained uterus is not screened endometrial carcinoma is not recommended. Although an increased risk is theoretically assumed hyperplasia and endometrial carcinoma due to aromatization of exogenous testosterone to estrogen with anovulation and thus the action of unopposed estrogen, there are no data on this. On the contrary, several studies have pointed to endometrial atrophy due to testosterone use. However, if abnormal uterine bleeding occurs, the approach is the same as in the general population - adequate follow-up.

In the case of breast cancer screening in FtM, it is important to know exactly what type of surgery has been performed: total mastectomy or breast tissue reduction only, and to choose the form of follow-up accordingly.

Masculinizing hormone therapy may also cause an increase in libido, oligo to amenorrhoea, vaginal atrophy and clitoral enlargement. Menses will begin to resolve within the first few months of treatment, however, if bleeding persists, adding gestagen to the treatment to accelerate

inducing amenorrhoea if the person wishes to avoid a hysterectomy. Testosterone causes vaginal atrophy - the vaginal mucosa is more fragile, more easily injured and the altered flora increases the risk of bacterial vaginosis, cystitis, cervicitis and dyspareunia. Vaginal atrophy

may also be the reason for the impossibility of a classical vaginal examination in vaginal mirrors. In these cases, local treatment with lubricants, vaginal moisturizers or local administration of estrogen is indicated, in which case it is necessary to carefully inform about its minimal systemic absorption, which does not interfere with the effect of testosterone.

### MtF preventive monitoring

Neovagina does not need regular cytological follow-up. However, it is important to remember that the neovagina is lined with skin, not mucous membranes, so natural lubrication is absent. In case of difficulties with dilatation of the neovagina, it is recommended to use more lubricant, a smaller dilator for more frequent and deeper dilatation, and then the gradual introduction of larger dilators.

In case of persistent pain or discomfort during dilation, consultation is recommended with a pelvic floor physiotherapist. There may also be problems with more frequent discharge and odour (sebum, dead skin cells, retained ejaculate or lubricant), adequate instruction on cleaning with soap and water is important. Bleeding or discharge due to granulation tissue may also be present, here topical treatment with silver nitrate preparations is effective.

Prostate cancer should be monitored according to current recommendations in the same way as in the general population.

The risk of breast cancer is assumed to be lower, but breast tissue is denser on mammography, resulting in a higher incidence of false-negative mammographic findings. It is generally recommended to begin breast cancer screening after **age 50 and at least 5 years of hormone therapy**.

### **Necessary components and prerequisites of comprehensive health management of an adult with dg. F64.0**

- access to comprehensive healthcare,
- detailed history (focusing on symptoms, course, timing, differential diagnosis),
- meticulous maintenance of medical records (including recording the initiation of individual interventions, signing informed consent for individual procedures),
- creation of an individual diagnostic plan and individual treatment plan for an adult with dg. F64.0,
- two-way information of the patient and the specialist,
- Supervision specialist at uncertainty - diagnostic, differential-diagnostic (psychiatrist-sexologist),
- Providing sufficient time and space for informed decisions (congruence in an open and confidential therapeutic relationship), support and counselling according to individual need,
- intensive multidisciplinary team collaboration during the complex health management of an adult with dg. F64.0,
- adherence to minimum durations for individual interventions and the periods between them, while at the same time  
not limiting the maximum duration; some examinations and procedures are limited in validity and must be repeated if the specified time interval is exceeded.
- Inclusion of the VLD or VLDD (for persons over 18 years of age in the care of the VLDD) in collaboration with the multidisciplinary team after the individual treatment plan has been established.

### **General recommendations for the provision of health care to adults with dg. F64.0**

At the first encounter of a person with suspected or confirmed dg. F64.0 with a specialist, it is important

a "gender neutral" environment to establish adequate trust and honest open conversation.

Provision of health care to adults with dg. F64.0, especially in the workplace, that are not specialized for this group of patients can lead to situations that are perceived as subjectively unpleasant by persons with dg F64.0. Such situations need to be prevented.

It is important that team members are encouraged to be supportive and understanding of the issues and are adequately educated on the health claims and specifics of people with dg. F64.0.

Site managers and all health workers should strive to ensure decent conditions and detect potential problems. If the material-technical and personnel resources of the inpatient facility allow it, when it is necessary to hospitalize a person with dg. F64.0 (at any stage of treatment), it is preferable to place him/her in a separate room, preferably with its own sanitary facilities (toilet and bathroom). If the situation does not allow it, look for

in cooperation with the person concerned, find the most suitable alternative (agree on a timetable for the use of shared bathrooms, etc.).

According to the code of ethics of a health care professional, when communicating with a patient, i.e. also a person with dg. F64.0, it is necessary to use a professional, non-judgmental approach, including the use of verbal and non-verbal means. Respect the wishes of the person with dg. F64.0 regarding preferred name and gender at every stage of the health care provided.

It is necessary to explain to her that the official medical documentation and the patient's designation for the needs of the staff must be kept according to the data in the identity card and the insurance card, but

in routine communication during hospitalisation or examinations, the name preferred and used by the patient may be used. When describing intimate body parts, when communicating with a person with dg. F64.0, it is recommended to use non-gender designations. Patients may have difficulty anatomically naming their primary or secondary sex characteristics. These names are best agreed upon together during prior communication with the patient. During physical examinations, care should be taken to maintain privacy and clear communication, informing the patient

about the individual operations in advance and during their course, evaluate the patient's emotional reactions continuously. This is particularly important for examinations that may be uncomfortable for the patient (e.g. gynaecological/urological).

Although every situation cannot be resolved to the patient's liking, it is important to show good will, effort, and respect in order to prevent stigma and negative patient experiences with the health care system (40, 41).

A member of the multidisciplinary team can also refer the person with dg F64.0 and their loved ones to a contact

with support groups and communities of citizens with similar life situations.

#### **Conditions for the issue of a Medical Opinion on the change of sex of a person :**

a) the diagnostic tests performed according to the standard procedure demonstrably confirm the diagnosis of F 64.0,

b) the person with transsexualism has signed an informed consent and

1. has undergone genital reassignment surgery or secondary sex characteristics,

or

2. has been on hormone treatment for at least one year and, with an interval of at least one year from the start of hormone treatment during which time she has lived in an opposite-sex role, has expressed in writing to the treating physician the fact that during that period she has acquired the belief that a permanent, lifelong and irreversible change of her legal identity, name and surname is the only possible solution for her; hormone treatment for at least one year shall not be required if it is contraindicated for a person with transsexualism.

In the event that hormone therapy is contraindicated, it cannot be administered without the consent of the person with dg. F64.0, surgery to alter the genital organs or secondary sex characteristics may be indicated. In this case, in order to issue a Medical Opinion on gender reassignment, the adult with dg F64.0 is required to undergo an RTL/RTE (including assessment of aesthetic changes towards a new role, change of name to a neutral name, external appearance, functioning in personal and professional life, subjective assessment of

the person's

acceptance by the environment, readiness for role change) for a minimum of one year, treatment of comorbidities, if present, and a consensual opinion of an interdisciplinary consortium composed of specialists: a psychiatrist with 5 years of experience/psychiatrist-sexologist, gynaecologist-obstetrician/urologist, endocrinologist) and a psychologist, who will provide the person with dg. F64.0, the chief specialist of the Ministry of Health for sexology (after his/her appointment) and an employee of the Ministry of Health as the secretary of the consilium. The interdisciplinary consortium is convened by the chief expert of the Ministry of Health of the Slovak Republic for sexology at the request of the attending physician - psychiatrist with 5 years of experience/psychiatrist-sexologist. The opinion of the interdisciplinary board becomes part of the medical documentation of the person with dg. F64.0. If the person with F64.0 has completed the diagnostic and intervention phase with a psychiatrist with less than 5 years' experience, he/she must be referred to the care of a psychiatrist with 5 years' experience/psychiatrist/sexologist before a medical opinion is issued.

### **Forecast**

According to current knowledge, it is a diagnostic entity that tends to persist for life. Treatment aimed at changing gender identity in the sense of matching with sex assigned at birth or genetic sex is not effective and is currently considered unethical (1, 12), and therefore requires comprehensive medical management. In the absence of health care, symptoms of gender dysphoria, depression, suicidal behaviour and symptoms of post-traumatic stress disorder may intensify

(29). A person with transsexualism in the absence of access to health care and intense desire after achieving change, may also reach for non-medically indicated or self-threatening procedures in an attempt to alleviate the suffering experienced. With adequate comprehensive management and good cooperation with the person dg. F64.0, based on a mutual doctor-patient concordance, the prognosis is favourable. As a rule, the person requires lifelong hormonal treatment, preventive monitoring also with focus on the condition after surgical interventions. Follow-up medical care according to the individual needs of persons with dg. F64.0 will contribute significantly to improving prognosis. The availability and accessibility of comprehensive medical management aims to alleviate the suffering that may be associated with dg. F64.0, improving quality of life and satisfactory integration into society (29).

### **Expert opinion (expertise, review, PZP, etc.)**

From the assessment point of view, the Social Insurance Company's assessing physicians assess the patient for the purposes of disability according to Annex No. 4 - Percentage rate of decrease in earning activity according to the type of disability of organs and systems, to Act No. 461/2003 Coll. on Social Insurance as amended. Transsexualism (F64.0) is classified in Chapter V - Mental illnesses and behavioural disorders, Item 5 - Personality and behavioural disorders, together with diagnoses F60 - F69, according to the above-mentioned Annex No 4. According to the severity of psychiatric symptoms

in the case of transsexualism due to a mismatch between inner experience and assigned gender, in conjunction with comorbidity, disability may be recognised with a rate of 80% reduction in earning capacity. The basis for the assessment of disability is the professional medical findings of psychiatrists and psychologists.

In dg. F64.0, temporary incapacity for work in the case of comorbidities or in connection with surgery is also addressed from a judgemental point of view.

The forensic assessment of the condition is individual and falls within the competence of the forensic expert.

## **Provision and organisation of care**

Care for people with dg. F64.0 is basically provided in an outpatient form. Inpatient care is provided in the case of surgical procedures and in the management of comorbidities requiring hospitalization.

Providers of outpatient care are psychiatric outpatient clinics, psychological, gynaecological, urological, surgical, plastic-surgical, endocrinological and possibly according to the individual needs of the patient and others with material - technical and personnel equipment according to the relevant legislation provide comprehensive health care, including preventive care. The first-contact doctor for an adult is a psychiatrist, a psychiatrist-sexologist or a VLD/VLDD (for persons over 18 years of age under the care of a VLDD ). If the VLD/VLDD detects symptoms of dg. F64.0, he/she refers the person for a psychiatric examination and carries out routine curative-preventive care throughout the diagnostic, intervention and follow-up phases. The first contact with an adult with dg. F64.0 may also be a clinical psychologist or psychologist who, after conducting a psychological examination, refers the person with suspected dg. F64.0 for a psychiatric examination. It is important that there is a mutual communication between the VLD/VLDD and the specialists cooperating in the above-mentioned multidisciplinary team, who at the same time provide comprehensive health care to the person with dg. F64.0.

Providers of inpatient care according to the relevant specialty (psychiatric, urological, gynaecological-obstetric, surgical and plastic-surgical, endocrinological, etc.) with material-technical and personnel equipment according to the relevant legislation provide complex health care that cannot be provided on an outpatient basis.

## **Further recommendations**

As the SSTP is only targeting adult age and diagnostic unit F64.0, it is necessary to develop appropriate SSTPs/SOPs for these other groups.

In the interest of humanizing health care, it is important to be non-discriminatory, non-stigmatizing, non-moralizing and non-pathologizing approach of all health professionals, therefore it is necessary to expand

Educational activities, expanding education in this area. It is also appropriate to target awareness-raising activities at the general population.

It is necessary to lift the indication restrictions for hormonal drugs for people with dg. F64.0, as they define their prescription according to biological sex. At the same time, it is necessary to provide for the extension of medical interventions that are not available in Slovakia, especially surgical interventions, and to create a SOP for them with reference to this NTP. It is also necessary to enable gynaecological (FtM) and urological (MtF) examinations to be carried out under public health insurance also for persons with F64.0 after an administrative sex change.

## **Special addition to the standard**

Annex 1: Confirmation of the course of treatment

Annex 2: Protocol for the process of diagnosis of an adult with dg. F64.0

Annex 3: Instructions and written informed consent of the patient pursuant to Section 6 of Act No. 576/2004 Coll.

z. on health care, services related to the provision of health care and on amendment and supplementation of certain acts, as amended

Flowchart 1: Diagnosis and complex management of health care for an adult with



transsexualism

## Recommendations for further audit and revision of the standard

The first planned audit and review of this standard procedure after two years, possibly after the 11th revision of the ICD in the Slovak Republic.

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***Remark:***

*If the clinical condition and special circumstances require a different approach to prevention, diagnosis or treatment than that outlined in this standard procedure, an alternative approach may be possible if further investigations, comorbidities or treatment are taken into account, i.e. an evidence-based approach or one based on clinical consultation or clinical consensus. Such clinical management should be clearly recorded in the patient's medical record.*

**Effectiveness**

This standard procedure shall enter into force on 3 March 2023.

**Vladimir Lengvarsky**  
Minister for Health

**Diagram 1: DIAGNOSIS AND COMPREHENSIVE MANAGEMENT OF HEALTH CARE FOR THE ADULT WITH TRANSEXUALISM**

