



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	February 9, 2016 February 24, 2016; January 21, 2022; June 16, 2022, March 13, 2023

**Testosterone (non-injectable formulations)**

**TOPICAL:**

- Clinical PA required (preferred): Androderm® patch, AndroGel® pump, Testosterone Pump (Axiron®), Testim® gel tube
- Clinical PA required (non-Preferred): Fortesta® gel pump, Natesto® nasal gel pump, Testosterone gel packet/pump/tubes, Testosterone topical solution, Vogelxo® gel packet/pump/tube

**IMPLANT:**

- Preferred: N/A
- Non-Preferred: Testopel®

**ORAL:**

- Preferred: N/A
- Non-Preferred: Jatenzo®, Tlando®

**LENGTH OF AUTHORIZATION:** One year

**INITIAL REVIEW CRITERIA:**

- Patient is ≥ 18 years old; AND
- Patient is male; AND
- Patient has a diagnosis of primary or secondary hypogonadism;\* AND
- Patient does not have a history of prostate carcinoma or male breast carcinoma; AND
- Prescriber has submitted the results of two separate serum testosterone levels, each drawn in the morning, which indicate a low serum testosterone (normal range: 300 to 1,000 ng/dL) within the last six months.

\* Causes of hypogonadism are classified as primary which are due to failure of the testes, or secondary, which are due to failure of the hypothalamus or pituitary gland. Either type of hypogonadism, may be caused by an inherited (congenital) or acquired factor.

\* Examples of primary male hypogonadism include but are not limited to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, chemotherapy, radiation therapy, toxic damage from alcohol or heavy metals, testicular infections (such as mumps) and chromosomal abnormalities such as Klinefelter’s Syndrome

\* Examples of secondary male hypogonadism include but are not limited to idiopathic gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency and pituitary hypothalamic injury from tumors, trauma, or radiation.

\*\* Safety and efficacy in men “age-related hypogonadism” has not been established.

**PATIENTS WHO MEET CRITERIA SHOULD BE APPROVED FOR THE PREFERRED AGENTS**

PI. Trial Ex. 027



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CONTINUATION OF THERAPY CRITERIA:

- Patient has been compliant with treatment based on refill history
- Prescriber submits labs within the last twelve months indicating patient has a normal serum testosterone level on therapy (normal range: 300-1,000 ng/dL)

DOSING & ADMINISTRATION:

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>

## Agency Responses to Plaintiffs' Questions: March 1, 2023

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**Plaintiffs' Question:** *Please provide a complete list of the diagnostic codes (ICD-10 codes) programmed in FMMIS for the following drugs (listed by generic name): estradiol (all formulations and combinations listed in the PDL); testosterone (all formulations listed in the PDL); testosterone cypionate (all formulations listed in the PDL); testosterone enanthate (all formulations listed in the PDL); triptorelin pamoate (both the kit and the vial); leuprolide acetate (all formulations listed in the PDL); Metformin HCL (all formulations listed in the PDL).*

**Agency Response:** The diagnosis codes for drugs subject to an automatic prior authorization or bypass are located at

[https://ahca.myflorida.com/medicaid/Prescribed\\_Drug/drug\\_criteria\\_pdf/Automated\\_PA.pdf](https://ahca.myflorida.com/medicaid/Prescribed_Drug/drug_criteria_pdf/Automated_PA.pdf).

This list includes those established for triptorelin pamoate and leuprolide acetate. For prescription drugs that are not on that list and do not require a prior authorization, the Agency does not verify the diagnosis code prior to paying the claim.

**Plaintiffs' Question:** *Please answer whether the prescribed drug criteria listed at [https://ahca.myflorida.com/6edicaid/prescribed\\_drug/drug\\_criteria.shtml](https://ahca.myflorida.com/6edicaid/prescribed_drug/drug_criteria.shtml) is an exhaustive list of the criteria relied upon by AHCA in reviewing whether a prescribed drug is medically necessary. If the above is not an exhaustive list, please provide documents indicating all other criteria on which AHCA relies in determining whether a prescribed drug is medically necessary for a particular patient, either during the prior authorization process, or after a claim has been paid (as described by Mr. Brackett).*

**Agency Response:** Yes, this is an exhaustive list.

**Plaintiffs' Question:** *Please answer whether Florida's Medicaid managed care plans are required to cover all drugs included in the PDL and, if so, whether the plans must follow the prior authorization requirements as indicated in the PDL.*

**Agency Response:** Yes, health plans participating in the Statewide Medicaid Managed Care program must cover all drugs on the Preferred Drug List and cannot be more restrictive when covering drugs that have a specific criteria.

**Plaintiffs' Question:** *Please identify the person who made edits to the GAPMS report on cross-sex hormone therapy dated May 20, 2022 as well as all individuals who accessed the document.*

**Agency Response:** The Agency identified the employee as Shantrice Greene, who worked as a senior pharmacist. She is no longer with the Agency.

**Plaintiffs' Question:** *Please provide the number of individuals who received Medicaid coverage for puberty suppression medications to treat gender dysphoria from January 1, 2015 to August 21, 2022.*

**Agency Response:** Please refer to the data file that was completed on March 1, 2023.

**Plaintiffs' Question:** *Please provide the number of grievances and the number of appeals filed with Florida Medicaid managed care plans regarding services excluded pursuant to Fla. Admin. Code R. 59G-1.050(7).*

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**Agency Response:** The Agency found one complaint regarding the coverage of services under the challenged exclusion.

**Plaintiffs' Question:** *Please state whether, and if so, how many, Medicaid fair hearings have resulted in a reversal of a decision to deny coverage for any of the services listed at 59G-1.050(7), prior to the effective date of the Challenged Exclusion.*

**Agency Response:** The Agency identified zero fair hearings that were prior to the challenged exclusion.

**Plaintiffs' Question:** *Please provide the number of Medicaid fair hearings regarding a request for coverage of services listed at 59G-1.050(7) since August 21, 2022 including information about the adverse action being appealed and the final outcome.*

**Agency Response:** The Agency identified zero fair hearings that occurred after the implementation of the challenged exclusion.

**Plaintiffs' Question:** *Please identify the Florida Department of Health employee(s) who provided the name "Michelle Cretella" or the name of any other consultant who AHCA relied upon or consulted with in the drafting of the 2022 GAPMS Memo.*

**Agency Response:** All communication that occurred between the Agency and the Department of Health occurred through verbal conversations. Agency staff that participated in these discussions do not recall the specific Department of Health employee who provided the name.

**Plaintiffs' Question:** *Please identify all individuals who AHCA considered but decided not to use for assistance with drafting the June 2022 GAPMS report on treatment for gender dysphoria.*

**Agency Response:** Agency staff engaged in verbal communications with individuals that were referred by Dr. Michelle Cretella and do not recall the names of those individuals that were consulted.

**Plaintiffs' Question:** *Regarding the emails between AHCA and Magellan dated April 20, 2022 to June 3, 2022 (Def\_000145166 to Def\_000145169), please answer the following:*

- **Question:** *What does CCM mean?*
- **Agency Response:** Change Control Memo
- **Question:** *What does "gender code = B (Both)" mean?*
- **Agency Response:** That a covered outpatient prescription drug can be prescribed to both males and females.
- **Question:** *What is the "internal Gender Dysphoria criteria?"*
- **Agency Response:** The criteria provided to Magellan to utilize when reviewing prior authorization requests for GnRH antagonists.
- **Question:** *What is meaning of the following paragraph: "This internal document serves for GnRH analog use to delay puberty in adolescents with Gender Dysphoria, but it does not speak to the use of hormone therapy (i.e. anastrozole, etc.). This document was provided by the Agency due to a fair hearing request received for Lupron for a recipient with this diagnosis. All requests*

*required vetting by AHCA before a final determination is made, and MMA will continue to do so as instructed.”*

- **Agency Response:** This paragraph specifically references the internal prior authorization review criteria for GnRH antagonists and requires Magellan only to review requests for that one drug category and not any that involve hormones such as testosterone or estrogen.





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organizations for the purpose of communicating, clarifying, or developing Medicaid policy.

- Representing the Agency, as assigned, in external or stakeholder/partner meetings.

This standard is met by performing all of the following:

- The response is drafted and begins routing within the timeframe assigned by the supervisor or the prescribed bureau response timeline (when applicable).
- The drafted response complies with the bureau style guide requirements (effective July 1, 2016).
- The drafted response did not have to be returned for substantial editing more than one (1) time through all levels of management review, up to the Bureau Chief, avoiding major delays in the assignment completion.
- Substantial edits modify the document's concept and intended use, audience, content (more than 50%), organization, design, and style.
- Research is linked and synthesized to answer the ask of the assignment.
- The response draft includes research and authority in the left side of the routing folder.
- The response is completed by the employee, without escalation to or intervention by management to address or prompt resolution of outstanding needs.
- The employee maintains assignments in ARTS and team One Drive tracking tool at a minimum weekly.

An exception is defined as an assignment where the bulleted standards above are not met. Holidays, competing priorities, sick leave, and annual leave may be taken into consideration with this expectation, by approval of the manager in consultation with the Bureau Chief.

#### Rating Methodology:

Score of 3: Employee has six - eight (6-8) exceptions to the bulleted expectations per evaluation period.

Score of 4: Employee has three - five (3-5) exceptions to the bulleted expectations per evaluation period.

Score of 5: Employee has one - two (1-2) exceptions to the bulleted expectations per evaluation period. Additionally, the employee consistently and proactively goes above and beyond to achieve this SMART goal, requiring no more than two (2) reminders, check ins, or management assistance to accomplish this SMART goal in its entirety.

Score of 2: Employee has nine - eleven (9-11) exceptions to the bulleted expectations per evaluation period.

Score of 1: Employee has twelve or more (12+) exceptions to the bulleted expectations per evaluation period.

#### Resources

Bureau Style Guide

Authority documentation (Code of Federal Regulations, State Statute, administrative code/rule, etc.)

Agency Coverage Policies and Fee Schedules

National Coding Guidelines and Best Practices (CMS, AMA, ADA, etc.)

<https://innovation.cms.gov/>

#### Performance

Expectation Rating

Comments

Jeff is consistent, accurate, and timely in his responses to policy assignments.

#### Performance Expectation

##### Rating

5 - Exceptional

##### Job Specific

#### 1.2 Goal #2: National Policy Research and Analysis

The employee consistently maintains education related to CMS federal policy guidance, innovations in health care coverage and reimbursement, and coding protocols for fee schedule and policy updates and accuracy. This is done by:

- Proactively reviewing, synthesizing, applying, and understanding annual (2019 and 2020) coding changes published by various credible sources related to medical coding, dental coding (if applicable), facility coding (if applicable) diagnosis coding, place of service coding, and modifiers.
- Registering and attend federal, state, and association trainings, webinars, and informational opportunities for any improvements or impacts to Medicaid Policy
- Analyzing federal and waiver draft/final rules and authorities for potential updates, impacts, and improvements to Florida Medicaid
- Registering (for automated notifications) and reviewing federal policy guidance and reviewing all CMS federal policy guidance during the performance period Federal policy guidance includes, but is not limited to:
  - Regulations: Regulations implement laws passed by Congress and are published in the Federal Register. There are a variety of regulatory actions, some involving public comment. Although the types of actions can vary, generally CMS

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- publishes a notice of proposed rule-making, solicits and considers public comments, and issues a final rule.
- o State Medicaid Director Letters: State Medicaid Director (SMD) letters further clarify and communicate policies set forth in regulations. They provide Medicaid-related guidance and clarify statutory and regulatory issues.
  - o State Health Official Letters: State Health Official (SHO) letters are similar to SMD letters, but they generally apply to both Medicaid and CHIP programs. Like SMD letters they provide guidance and clarify statutory and regulatory issues.
  - o Frequently Asked Questions: Frequently Asked Questions (FAQ) can clarify and provide guidance on regulatory or sub-regulatory issues. They can also be used to address operational and technical issues. In addition to the point-in-time releases, CMS also offers an interactive FAQ library.
  - o Center for Medicaid & CHIP Services (CMCS) Informational Bulletins: CMCS Informational Bulletins (CIBs) share information, address operational and technical issues, and highlight initiatives or related efforts. CIBs do not establish new policy or issue new guidance.
  - o CMS Innovation Center: webinars, trainings, and guidance documents (includes the Innovation Accelerator Program)
  - o U.S. Department of Health and Human Services Office of the Inspector General Reports and Publications
- Routinely review all OIG CMS reports to see what is vulnerable and is prone to weaknesses and review/analyze in relation to Florida Medicaid covered services, providers, and application of federal/state policies
- o MACPAC reports and recommendations
    - Researching, reviewing, and utilizing nationally adopted toolkits and quality metrics to inform and develop improved outcomes for recipients through covered services in the Florida Medicaid program
    - If made available by the Florida Bureau of Medicaid Program Integrity, employee attends all sessions related to a Medicaid Integrity Institute Training and applies lessons learned to assigned policy and fee schedule areas.

Holidays, competing priorities, sick leave, and annual leave may be taken into consideration with this expectation, by approval of the manager in consultation with the Bureau Chief.

This standard is met by performing all of the following for all assigned or available National Policy Research (within the employee's assigned subject areas):

- A summary (including impacts) is drafted and begins routing within the timeframe assigned by the supervisor or the prescribed bureau response timeline (when applicable).
- The summary (including impacts) complies with the bureau style guide requirements (effective July 1, 2016).
- The summary of the national policy research did not have to be returned for substantial editing more than one (1) time through all levels of management review, up to the Bureau Chief, avoiding major delays in the assignment completion.
- o Substantial edits modify the document's concept and intended use, audience, content (more than 50%), organization, design, and style.
- Research is complete, linked, and synthesized to potential innovations and updates in the Medicaid program.
- The summary includes authorities, any stakeholder/provider feedback, research, and authority in the left side of the routing folder.
- The summary is completed by the employee, without escalation to or intervention by management to address or prompt resolution of outstanding needs.
- The employee maintains an electronic folder and paper binder of all potential, optional, required, and necessary updates to each assigned service specific with national research and opportunities for improvement.
- o The employee will present the information detailed in the folder/binder to team members, leadership and other Agency staff as scheduled.

An exception is defined as an assignment where the bulleted standards above are not met. Holidays, competing priorities, sick leave, and annual leave may be taken into consideration with this expectation, by approval of the manager in consultation with the Bureau Chief.

#### Rating Methodology:

- Score of 3: Employee drafts document related to their assigned policies, with four – five (4-5) exceptions.
- Score of 4: Employee drafts document related to their assigned policies, with three (3) exceptions.
- Score of 5: Employee drafts document related to their assigned policies, with no more than two (2) exceptions. Additionally, the employee consistently and proactively goes above and beyond to achieve this SMART goal, requiring no more than two (2) reminders, check ins, or management assistance to accomplish this SMART goal in its entirety.
- Score of 2: Employee drafts document related to their assigned policies with no more than six (6) exceptions.
- Score of 1: Employee drafts document related to their assigned policies with no more than seven (7) or more exceptions.

#### Resources

2098 and 2020 books (ICD-10, UB-04, CPT, and CDT)

MII Trainings: <https://www.justice.gov/mii/training>

CMS Federal Policy Guidance: <https://www.medicaid.gov/federal-policy-Guidance/index.html>

Register to receive CMS Updates automatically via email:

<https://public.govdelivery.com/accounts/USCMSMEDICAID/subscriber/qualify?email=>





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An exception is defined as an assignment where the bulleted standards above are not met. Holidays, sick and annual leave will be taken into consideration with this expectation, by approval of the manager in consultation with the Bureau Chief.

#### Rating Methodology:

Score of 3: Employee has five - six (5-6) exceptions to the bulleted expectations per evaluation period.

Score of 4: Employee has three - four (3-4) exceptions to the bulleted expectations per evaluation period.

Score of 5: Employee has one - two (1-2) exceptions to the bulleted expectations per evaluation period. Additionally, the employee consistently and proactively goes above and beyond to achieve this SMART goal, requiring no more than two (2) reminders, check ins, or management assistance to accomplish this SMART goal in its entirety.

Score of 2: Employee has seven - eight (7-8) exceptions to the bulleted expectations per evaluation period.

Score of 1: Employee has nine or more (9+) exceptions to the bulleted expectations per evaluation period.

#### Resources

##### Bureau Style Guide

Authority documentation (Code of Federal Regulations, State Statute, administrative code/rule, etc.)

Population health data includes but is not limited to:

- National data sets and analyses (SAMSHA, CMS, MACPAC, etc.)
- Request from Medicaid Data Analytics (MEDICAIDANALYTICSREQUEST@ahca.myflorida.com)
- Peer-reviewed journal articles
- <https://innovation.cms.gov/>
- Request from the Medicaid Complaint Hub and Fair Hearing (for data/information):

Performance Expectation Rating Comments	Jeff exceeds expectations with ensuring that requests for coverage determination, pursuant to the generally accepted professional medical standards (GAPMS) rule or other requests, are completed timely and are of good quality.
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#### Performance Expectation

##### Rating

5 - Exceptional

##### Job Specific

#### 1.4 Goal #4: Timely and Accurate Completion of Special Projects

The employee ensures that requests for special projects are accurate, processed timely, and is of good quality.

This standard is met by performing all of the following:

- Performs research related to legislative request, media inquiries, and coverage determinations to allow informed decisions making.
- The response is drafted and begins routing within the timeframe assigned by the supervisor or the prescribed bureau response timeline (when applicable).
- The drafted response complies with the bureau style guide requirements (effective July 1, 2016).
- The drafted response did not have to be returned for substantial editing more than one (1) time through all levels of management review, up to the Bureau Chief, avoiding major delays in the assignment completion.

An exception is defined as an assignment where the bulleted standards above are not met.

- The GA II maintains a technical assistance tool or Ad/Hoc log in a prescribed format, containing all special projects/issues submitted.
- Questions and answers/status of resolution will be indicated on spreadsheet and made available to management for weekly review.
- Submission date of questions/issue must be notated on tool as well.
- Those significant changes, questions, and/or issues that require research and/or referral must be documented on the tool on a weekly basis by COB every Friday.
- Holidays, sick and annual leave will be taken into consideration with this expectation, by approval of the manager in consultation with the Bureau Chief.

#### Rating Methodology:

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Score of 3: Employee documents the provision of technical assistance weekly by COB, Friday reflecting adherence to the above standards with no more than four (4) exceptions bi-annually to the bulleted expectations or no more than six (6) exceptions annually to the bulleted expectations.

Score of 4: Employee documents the provision of technical assistance weekly by COB, Friday reflecting adherence to the above standards with less than three (3) exceptions to the bulleted expectations per evaluation period.

Score of 5: Employee documents the provision of technical assistance weekly by COB, Friday reflecting adherence to the above standards with no more than two (2) exceptions. Additionally, the employee consistently and proactively goes above and beyond to achieve this SMART goal, requiring no more than two (2) reminders, check ins, or management assistance to accomplish this SMART goal in its entirety.

Score of 2: Employee documents the provision of technical assistance weekly by COB, Friday reflecting adherence to the above standards with three (3) to five (5) exceptions to the bulleted expectations per evaluation period.

Score of 1: Employee documents the provision of technical assistance weekly by COB, Friday reflecting adherence to the above standards with six (6) or more exceptions to the bulleted expectations per evaluation period.

#### Measurement

- Employee documents the provision of technical assistance weekly by COB, Friday.
- Technical assistance tool, Ad/Hoc log and work plan maintained by the employee in accordance with Bureau procedures.
- Assignment submission and approval as document on SharePoint Routing web page.

#### Resources

Bureau Style Guide

Technical assistance tool or Ad/Hoc log

Performance Expectation Rating     Jeff completes special projects timely and accurately.  
Comments

#### Performance Expectation Rating

4 - Above Expectation

#### Job Specific

#### 1.5 Goal #5: Project Management and Work Plans

The employee ensures that all projects, assignments, requests for policy clarification, correspondence, and language are in support of and prioritized alongside the Agency's goals. This includes is the planning, organizing and managing the effort to accomplish a successful project. Project planning, also called project management, includes developing a project plan, which involves defining and confirming the project goals and objectives, how they will be achieved, identifying tasks and quantifying the resources needed, and determining budgetary impacts and timelines for completion. It also includes managing the implementation of the project plan, revising as needed.

This standard is met by performing all of the following:

- All steps for each project are proposed by the employee, including the employee taking lead on a project (or following a peer that is lead on a project)
- The draft for the timelines and milestones are coordinated with the Federal Authorities team (for all SPA updates) and/or the Rules Unit (for all rule updates)
- The draft timeline and milestones incorporate considerations and buffers for other Agency goals, projects, and recurring events (e.g. legislative session)
- The employee reviews the proposed timeline with their manager for approval.
- Each step is detailed on the employees Work Plan (Section Tracker).
- The Work Plan is minimally updated by close of business, the end of the work week each week.
- The Work Plan updates are made across all items (cells).
- The employee follows up consistently with their manager and other leadership to ensure their project moves forward. This includes pending reviews and upcoming deadlines.
- Additional changes and updates to the Work Plan are made within the timeframe assigned by the supervisor or the prescribed bureau timeline (when applicable).
- The Work Plan and Timeline drafts and updates are completed by the employee, without escalation to or intervention by management to address or prompt resolution of outstanding needs.

An exception is defined as an assignment where the bulleted standards above are not met. Holidays, competing priorities,



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sick leave, and annual leave may be taken into consideration with this expectation, by approval of the manager in consultation with the Bureau Chief.

**Rating Methodology:**

Score of 3: Employee has five - six (5-6) exceptions to the bulleted expectations per evaluation period.

Score of 4: Employee has three - four (3-4) exceptions to the bulleted expectations per evaluation period.

Score of 5: Employee has one - two (1-2) exceptions to the bulleted expectations per evaluation period. Additionally, the employee consistently and proactively goes above and beyond to achieve this SMART goal, requiring no more than two (2) reminders, check ins, or management assistance to accomplish this SMART goal in its entirety.

Score of 2: Employee has seven - eight (7-8) exceptions to the bulleted expectations per evaluation period.

Score of 1: Employee has nine or more (9+) exceptions to the bulleted expectations per evaluation period.

**Resources**

Work Plan on the One Drive

<https://www.projectinsight.net/project-management-basics/>

<https://managementhelp.org/projectmanagement/index.htm>

**Performance**

Expectation Rating This goal was not applicable.

Comments

**Performance Expectation**

Rating

None Given

**Overall Manager Comments**

Comments

**Second-Level Manager Comments**

Comments

**Summary**

**Overall Rating**

4.50 - Outstanding

4.50 - Outstanding

**Expectations Acknowledgement**

Manager Acknowledgement on Behalf of Employee

Manager Acknowledgement Comments

I Acknowledge Receipt of My Performance Expectations Yes

Date Acknowledged 09/18/2020

**Evaluation Acknowledgement**

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Manager Acknowledgement on Behalf  
of Employee

Manager Acknowledgement Comments

I Acknowledge Receipt of My  
Performance Evaluation                      Yes

Date Acknowledged                              08/13/2021

Employee Acknowledgement  
Comments    Thanks.



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2021-2022 Performance Plan for JEFFREY ENGLISH



## 2021-2022 Performance Plan for JEFFREY ENGLISH

### Employee Information

First Name	JEFFREY	Agency	AHCA - Agency for Hlth Care Ad (6800)
Middle Name		Organization Code	684060000000000000000000
Last Name	ENGLISH	Agency Hire Date	09/06/2019
Position Title	GOVERNMENT ANALYST II	Login ID	01456927

### Performance Plan Period

Originator	SF ADMIN (SFADMIN)
Review Period	07/01/2021 - 06/30/2022
Due Date	08/29/2022

### Performance Expectations

Job Specific

#### 1.1 Goal #1: Communication

The employee ensures that assignments and requests for policy clarification, correspondence, and language are accurate, clear, concise, processed timely, and are of good quality alongside and in support of detailed research. This includes, but is not limited to, oral, written, and presentation of:

- Questions from Agency staff (not redirected to the Medicaid Policy inbox for assignment)
- Internal and external stakeholder joint initiatives, assignments, questions, and projects
- CorrFlow assignments, questions, and projects
- Medicaid Policy Inbox assignments, questions, and projects
- Medicaid Director's Office assignments, questions, and projects
- Medicaid Program Integrity policy certifications
- Statewide Medicaid Managed Care report guide
- Contract and amendment language/review
- Dear Managed Care Plan letters
- Contract interpretations
- Policy transmittals
- Provider alerts
- Training documents/slides
- Decision points (including fiscal analyses)
- Legislative related assignments including:
  - o complete bill analyses including fiscal analysis set up, discussion, and follow through with Medicaid Program Finance
  - o associated documentation (i.e. impact section by section, bill check list, etc.)
  - o summary bill analysis (short form)
  - o no impact reviews
  - o legislative reports

As well as timely and accurately handling:

- Meetings and webinars to resolve complex issues or projects as they occur
- Serving as a subject matter expert and providing consultation to assist with the development or finalization of work products, including interagency agreements.
- Communicating effectively in a variety of ways that exhibits the employee's ability to clearly and accurately provide information and technical assistance to co-workers.
- Coordinating and lead meetings within the Agency, between the Agency and other state agencies, or with other

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organizations for the purpose of communicating, clarifying, or developing Medicaid policy.

- Representing the Agency, as assigned, in external or stakeholder/partner meetings.

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- The drafted response did not have to be returned for substantial editing more than one (1) time through all levels of management review, up to the Bureau Chief, avoiding major delays in the assignment completion.
- Substantial edits modify the document's concept and intended use, audience, content (more than 50%), organization, design, and style.
- Research is linked and synthesized to answer the ask of the assignment.
- The response draft includes research and authority in the left side of the routing folder.
- The response is completed by the employee, without escalation to or intervention by management to address or prompt resolution of outstanding needs.
- The employee maintains assignments in ARTS and team One Drive tracking tool at a minimum weekly.

An exception is defined as an assignment where the bulleted standards above are not met. Holidays, competing priorities, sick leave, and annual leave may be taken into consideration with this expectation, by approval of the manager in consultation with the Bureau Chief.

#### Rating Methodology:

Score of 3: Employee has six - eight (6-8) exceptions to the bulleted expectations per evaluation period.

Score of 4: Employee has three - five (3-5) exceptions to the bulleted expectations per evaluation period.

Score of 5: Employee has one - two (1-2) exceptions to the bulleted expectations per evaluation period. Additionally, the employee consistently and proactively goes above and beyond to achieve this SMART goal, requiring no more than two (2) reminders, check ins, or management assistance to a

Performance	Jeff completed all communication above
Expectation Rating	expectation.
Comments	

#### Performance Expectation Rating

4 - Above Expectation

#### Job Specific

#### 1.2 Goal #2: National Policy Research and Analysis

The employee consistently maintains education related to CMS federal policy guidance, innovations in health care coverage and reimbursement, and coding protocols for fee schedule and policy updates and accuracy. This is done by:

- Proactively reviewing, synthesizing, applying, and understanding annual (2019 and 2020) coding changes published by various credible sources related to medical coding, dental coding (if applicable), facility coding (if applicable) diagnosis coding, place of service coding, and modifiers.
- Registering and attend federal, state, and association trainings, webinars, and informational opportunities for any improvements or impacts to Medicaid Policy
- Analyzing federal and waiver draft/final rules and authorities for potential updates, impacts, and improvements to Florida Medicaid
- Registering (for automated notifications) and reviewing federal policy guidance and reviewing all CMS federal policy guidance during the performance period Federal policy guidance includes, but is not limited to:
  - Regulations: Regulations implement laws passed by Congress and are published in the Federal Register. There are a variety of regulatory actions, some involving public comment. Although the types of actions can vary, generally CMS publishes a notice of proposed rule-making, solicits and considers public comments, and issues a final rule.
  - State Medicaid Director Letters: State Medicaid Director (SMD) letters further clarify and communicate policies set forth in regulations. They provide Medicaid-related guidance and clarify statutory and regulatory issues.
  - State Health Official Letters: State Health Official (SHO) letters are similar to SMD letters, but they generally apply to both Medicaid and CHIP programs. Like SMD letters they provide guidance and clarify statutory and regulatory issues.
  - Frequently Asked Questions: Frequently Asked Questions (FAQ) can clarify and provide guidance on regulatory or sub-regulatory issues. They can also be used to address operational and technical issues. In addition to the point-in-time releases, CMS also offers an interactive FAQ library.
  - Center for Medicaid & CHIP Services (CMCS) Informational Bulletins: CMCS Informational Bulletins (CIBs) share

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information, address operational and technical issues, and highlight initiatives or related efforts. CIBs do not establish new policy or issue new guidance.

- o CMS Innovation Center: webinars, trainings, and guidance documents (includes the Innovation Accelerator Program)
- o U.S. Department of Health and Human Services Office of the Inspector General Reports and Publications
- ? Routinely review all OIG CMS reports to see what is vulnerable and is prone to weaknesses and review/analyze in relation to Florida Medicaid covered services, providers, and application of federal/state policies
- o MACPAC reports and recommendations
  - Researching, reviewing, and utilizing nationally adopted toolkits and quality metrics to inform and develop improved outcomes for recipients through covered services in the Florida Medicaid program
  - If made available by the Florida Bureau of Medicaid Program Integrity, employee attends all sessions related to a Medicaid Integrity Institute Training and applies lessons learned to assigned policy and fee schedule areas.

Holidays, competing priorities, sick leave, and annual leave may be taken into consideration with this expectation, by approval of the manager in consultation with the Bureau Chief.

This standard is met by performing all of the following for all assigned or available National Policy Research (within the employee's assigned subject areas):

- A summary (including impacts) is drafted and begins routing within the timeframe assigned by the supervisor or the prescribed bureau response timeline (when applicable).
- The summary (including impacts) complies with the bureau style guide requirements (effective July 1, 2016).
- The summary of the national policy research did

Performance Expectation Rating Comments	Jeff has done an excellent job of researching and analyzing national policies. He is Policy's lead on all NAMD calls and provides thorough and comprehensive notes and analysis to Agency leadership.
---	---

### Performance Expectation Rating

5 - Exceptional

Job Specific

### 1.3 Goal #3: Timely Processing of Requests for Coverage Determinations (GAPMS)

The employee ensures that requests for coverage determination, pursuant to the generally accepted professional medical standards (GAPMS) rule or other requests, are completed timely and are of good quality.

This standard is met by performing all of the following:

- The response is drafted and begins routing within the timeframe assigned by the supervisor or the prescribed bureau response timeline (when applicable).
- Each GAPMS request is reviewed within 5 business days of receipt in the Health Services Research email inbox, including use of the current decision tree checklist for initial routing determination (GAPMS vs decision point/coverage determination).
- The drafted response complies with the current GAPMS template, APA and Bureau style guide requirements (effective July 1, 2016).
- Research is completed prior to, during, and (if needed) after report drafting for continuous quality improvement, including:
  - o Reviewing, researching, drafting, and leading leadership walkthroughs for decision points for major changes in coverage policies and fee schedules
  - o Researching health care and relevant industry trends that may improve/have an impact on Florida Medicaid or may inform policy development activities
  - o Routinely reviewing and research Medicare policies, national Medicaid-related research and demonstration projects, Medicaid medical assistance program innovations for general and special populations, and alternative financing and service delivery systems models for innovation, updates, or impacts to Medicaid Policy
  - o Researching population health for each covered service area including routinely requested service/project/initiative specific Medicaid complaint hub data, MDA claims data (FFS and encounter)
  - o Submitting approved GPAMS information to the correct team member for addition to the service specific coverage policy and fee schedule within two business days of approval.
  - o Researching and reviewing current publications (e.g., Publication Manual of the American Psychological Association) related to currently covered or potentially covered services in the Florida Medicaid program



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- o Continuously researching evidence-based clinical practice guidelines, published reports and articles in the authoritative medical and scientific literature related to the health service (published in peer-reviewed scientific literature generally recognized by the relevant medical community or practitioner specialty associations), effectiveness of the health service in improving the individual's prognosis or health outcomes, utilization trends, coverage policies by other creditable insurance payor sources, recommendations or assessments by clinical or technical experts on the subject or field to infuse innovation and update coverage policies
- o Researching to find and develop resources for improvement and the development of Agency FFS reimbursement methodologies for covered services
- o The drafted response did not have to be returned for substantial editing more than one (1) time through all levels of management review, up to the Bureau Chief, avoiding major delays in the assignment completion.
- o Substantial edits modify the document's concept and intended use, audience, content (more than 50%), organization, design, and style.
- o The response draft includes pertinent research (reference summary) and authority (if applicable, for coverage determinations) in the left side of the routing folder.
- o The response is completed by the employee, without escalation to or intervention by management to address or prompt resolution of outstanding needs.
- o The employee maintains assignments in the GAPMS que (SharePoint site and Work Plan) and emails a summary to their manager at a minimum weekly.

An exception is defined as an assignment where the bulleted standards above are not met. Holidays, sick and annual leave will be taken into consideration with this expectation, by approval of the manager in consultation with t

Performance	Jeff has completed all GAPMS request in
Expectation Rating	an expedient manner, including all
Comments	expedited GAMPS.

## Performance Expectation Rating

5 - Exceptional

Job Specific

### 1.4 Goal #4: Timely and Accurate Completion of Special Projects

The employee ensures that requests for special projects are accurate, processed timely, and is of good quality.

This standard is met by performing all of the following:

- o Performs research related to legislative request, media inquiries, and coverage determinations to allow informed decisions making.
- o The response is drafted and begins routing within the timeframe assigned by the supervisor or the prescribed bureau response timeline (when applicable).
- o The drafted response complies with the bureau style guide requirements (effective July 1, 2016).
- o The drafted response did not have to be returned for substantial editing more than one (1) time through all levels of management review, up to the Bureau Chief, avoiding major delays in the assignment completion.

An exception is defined as an assignment where the bulleted standards above are not met.

- o The GA II maintains a technical assistance tool or Ad/Hoc log in a prescribed format, containing all special projects/issues submitted.
- o Questions and answers/status of resolution will be indicated on spreadsheet and made available to management for weekly review.
- o Submission date of questions/issue must be notated on tool as well.
- o Those significant changes, questions, and/or issues that require research and/or referral must be documented on the tool on a weekly basis by COB every Friday.
- o Holidays, sick and annual leave will be taken into consideration with this expectation, by approval of the manager in consultation with the Bureau Chief.

Rating Methodology:

Score of 3: Employee documents the provision of technical assistance weekly by COB, Friday reflecting adherence to the above standards with no more than four (4) exceptions bi-annually to the bulleted expectations or no more than six (6) exceptions annually to the bulleted expectations.

Score of 4: Employee documents the provision of technical assistance weekly by COB, Friday reflecting adherence to the

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above standards with less than three (3) exceptions to the bulleted expectations per evaluation period.

Score of 5: Employee documents the provision of technical assistance weekly by COB, Friday reflecting adherence to the above standards with no more than two (2) exceptions. Additionally, the employee consistently and proactively goes above and beyond to achieve this SMART goal, requiring no more than two (2) reminders, check ins, or management assistance to accomplish this SMART goal in its entirety.

Score of 2: Employee documents the provision of technical assistance weekly by COB, Friday reflecting adherence to the above standards with three (3) to five (5) exceptions to the bulleted expectations per evaluation period.

Score of 1: Employee documents the provision of technical assistance weekly by COB, Friday reflecting adherence to the above standards with six (6) or more exceptions to the bulleted expectations per evaluation period.

#### Measurement

- Employee documents the provision of technical assistance weekly by COB, Friday.
- Technical assistance tool, Ad/Hoc log and work plan maintained by the employee in accordance with Bureau procedures.
- Assignment submission and approval as document on SharePoint Routing web page.

#### Resources

Bureau Style Guide

Technical assistance tool or Ad/Hoc log

?

#### Performance

Expectation Rating      Jeff has completed all special projects quickly and thoroughly.

Comments

### Performance Expectation

#### Rating

4 - Above Expectation

#### Job Specific

### 1.5 Goal #5: Project Management and Work Plans

The employee ensures that all projects, assignments, requests for policy clarification, correspondence, and language are in support of and prioritized alongside the Agency's goals. This includes is the planning, organizing and managing the effort to accomplish a successful project. Project planning, also called project management, includes developing a project plan, which involves defining and confirming the project goals and objectives, how they will be achieved, identifying tasks and quantifying the resources needed, and determining budgetary impacts and timelines for completion. It also includes managing the implementation of the project plan, revising as needed.

This standard is met by performing all of the following:

- All steps for each project are proposed by the employee, including the employee taking lead on a project (or following a peer that is lead on a project)
- The draft for the timelines and milestones are coordinated with the Federal Authorities team (for all SPA updates) and/or the Rules Unit (for all rule updates)
- The draft timeline and milestones incorporate considerations and buffers for other Agency goals, projects, and recurring events (e.g. legislative session)
- The employee reviews the proposed timeline with their manager for approval.
- Each step is detailed on the employees Work Plan (Section Tracker).
- The Work Plan is minimally updated by close of business, the end of the work week each week.
- The Work Plan updates are made across all items (cells).
- The employee follows up consistently with their manager and other leadership to ensure their project moves forward. This includes pending reviews and upcoming deadlines.
- Additional changes and updates to the Work Plan are made within the timeframe assigned by the supervisor or the prescribed bureau timeline (when applicable).
- The Work Plan and Timeline drafts and updates are completed by the employee, without escalation to or intervention by management to address or prompt resolution of outstanding needs.

An exception is defined as an assignment where the bulleted standards above are not met. Holidays, competing priorities, sick leave, and annual leave may be taken into consideration with this expectation, by approval of the manager in consultation with the Bureau Chief.

Rating Methodology:



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Score of 3: Employee has five - six (5-6) exceptions to the bulleted expectations per evaluation period.  
 Score of 4: Employee has three - four (3-4) exceptions to the bulleted expectations per evaluation period.  
 Score of 5: Employee has one - two (1-2) exceptions to the bulleted expectations per evaluation period. Additionally, the employee consistently and proactively goes above and beyond to achieve this SMART goal, requiring no more than two (2) reminders, check ins, or management assistance to accomplish this SMART goal in its entirety.  
 Score of 2: Employee has seven - eight (7-8) exceptions to the bulleted expectations per evaluation period.  
 Score of 1: Employee has nine or more (9+) exceptions to the bulleted expectations per evaluation period.

**Resources**

Work Plan on the One Drive

<https://www.projectinsight.net/project-management-basics/>  
<https://managementhelp.org/projectmanagement/index.htm>

Performance Expectation Rating Comments	Jeff has maintained a complete and current listing of all GAPMS.
---	--

**Performance Expectation Rating**

4 - Above Expectation

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**Overall Manager Comments**

Comments	Jeff's research and insight has been a valuable asset to Medicaid Policy. He has unmatched research skills and provides a great deal of analysis and information on Medicaid Policy.
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**Second-Level Manager Comments**

Comments

**Summary**

**Overall Rating**

4.40 - Commendable

4.40 - Commendable

**Expectations Acknowledgement**

Manager Acknowledgement on Behalf of Employee

Manager Acknowledgement Comments

I Acknowledge Receipt of My Performance Expectations	Yes
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Date Acknowledged	07/01/2021
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**Evaluation Acknowledgement**

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2021-2022 Performance Plan for JEFFREY ENGLISH

Manager Acknowledgement on Behalf  
of Employee

Manager Acknowledgement Comments

I Acknowledge Receipt of My  
Performance Evaluation                      Yes

Date Acknowledged                              08/15/2022

Employee Acknowledgement  
Comments

**English, Jeffrey**

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**From:** English, Jeffrey  
**Sent:** Tuesday, March 22, 2022 4:55 PM  
**To:** Pickle, Devona  
**Subject:** RE: Investigational/experimental denial request from SHP Encrypt CPT Code 20985

Hey,

Yeah. I think of it as a minimum threshold to meet for coverage, so to speak. So we say if it "passes" GAPMS, it's covered and if it fails it's not. I get your point. Seems like the public and the plans are sometimes pulling in opposite directions.

**From:** Pickle, Devona <Devona.Pickle@ahca.myflorida.com>  
**Sent:** Tuesday, March 22, 2022 4:51 PM  
**To:** English, Jeffrey <Jeffrey.English@ahca.myflorida.com>  
**Subject:** RE: Investigational/experimental denial request from SHP Encrypt CPT Code 20985

Interesting. I went back to read the GAPMS rule... it's for requesting coverage—not disputing it.

(3) Health services that are covered under the Florida Medicaid program are described in the respective coverage and limitations handbooks, policies, and fee schedules, which are incorporated by reference in the F.A.C. The public may request a health service be considered for coverage under the Florida Medicaid program by submitting a written request via e-mail to HealthServiceResearch@ahca.myflorida.com. The request must include the name, a brief description, and any additional information that supports coverage of the health service, including sources of reliable evidence as defined in paragraph 59G-1.010(84)(b), F.A.C.

D.D. Pickle  
(office) 850-412-4646

**From:** English, Jeffrey <Jeffrey.English@ahca.myflorida.com>  
**Sent:** Tuesday, March 22, 2022 4:34 PM  
**To:** Dalton, Ann <Ann.Dalton@ahca.myflorida.com>; Pickle, Devona <Devona.Pickle@ahca.myflorida.com>; Bottcher, Jesse <Jesse.Bottcher@ahca.myflorida.com>  
**Subject:** Investigational/experimental denial request from SHP Encrypt CPT Code 20985

Hi Ann,

Simply is approving code 27447 Total Knee Arthroplasty.

1

Pl. Trial Ex. 030

20985 (Computer-Assisted Musculoskeletal Surgical Navigational Orthopedic Procedures of the Appendicular System) is an add-on code for certain surgical procedures of the knee, hip, shoulder, etc. The plan is denying that add-on code as experimental/investigational.

20985 is on Florida's fee schedule, as well as 40+ other states. There is no way for me to tell in Policy Reporter which surgical procedure the states that include the add-on code on their respective fee schedules are applying it to.

Most of the major insurance companies consider 20985 experimental/investigational, particularly as it applies to knee arthroplasty. There seems to be a separate body of literature depending upon which part of the body it is being considered for. It might meet GAPMS standards for a hip or a shoulder, but the body of literature pertaining to its use with knee arthroplasty is neither extensive nor of high quality. The best evidence seems to indicate that the use of Computer-Assisted Musculoskeletal Surgical Navigational Orthopedic Procedures shortens the duration of the procedure, but there is no convincing data indicating it speeds recovery, return to work/activity, or any other outcome meaningful to patients.

I believe we agree with the plan on this denial. I will crank out a report as quickly as I can and will have it tomorrow. I will send it to you for your review and approval.

Please let me know if you have any questions.

Jeff

State	Medicaid Coverage for Children					Illegal under State Law	Settlement or Court Judgment	
	Puberty Blockers*	HRT*	Top Surgery*	Bottom Surgery*				
AL	N	N	N	N		2022		
AK	C	C	C	C			2021	No ages specified
AZ	E	E	E	E		2010		
AK	E	E	E	E		2021	2001	
CA	C	C	C	C			2001	WPATH standards
CO	C	C	C	C				No ages specified
CT	C	C	C - 18 y.o.	C - 18 y.o.			2015	
DE	N	N	N	N				
DC	C	C	C - 18 y.o.	C - 18 y.o.				
FL	N	N	N	N				
GA	E	E	E	E				
HI	E	E	E	E				
ID	N	N	N	N				
IL	N	N	N	N				Covered for ages 21 and older
IN	N	N	N	N				
IA	N	N	N	N		2019	2021	State law overturned in 2021
KS	N	N	N	N				
KY	E	E	E	E				
LA	N	N	N	N				Medicaid MCO's do cover
ME	C	C	C	C			2019	All ages covered with PA.
MD	C	C	C - 18 y.o.	C - 18 y.o.				
MA	C	C	C - 18 y.o.	C - 18 y.o.				
MI	C	C	C	C				WPATH Standards, no ages specified
MN	C	C	C - 18 y.o.	C - 18 y.o.			2016	
MS	N	N	N	N				
MO	E	E	E	E				
MT	C	C	C	C				WPATH Standards, no ages specified
NE	E	E	E	E				
NV	C	C	C - 18 y.o.	C - 18 y.o.				
NH	C	C	C	C				No ages specified
NJ	C	C	C	C				No ages specified
NM	N	N	N	N				
NY	C	C - 16 y.o.	C - 18 y.o.	C - 18 y.o.				
NC	N	N	N	N				
ND	C	C	C - 18 y.o.	C - 18 y.o.				
OH	E	E	E	E				Not enforced
OK	N	N	N	N				
OR	C	C	C - 15 y.o.	C - 15 y.o.				Legal age of medical consent is 15 y.o.
PA	C	C	C	C				WPATH Standards, no ages specified
RI	C	C	C - 18 y.o.	C - 18 y.o.				
SC	N	N	N	N				
SD	N	N	N	N				
TN	E	E	E	E				
TX	E	E	E	E				
UT	N	N	N	N				Medicaid MCO's do cover
VT	C	C	C	C				No ages specified
VA	N	N	N	N				
WA	C	C	C	C				No ages specified
WV	N	N	N	N				
WI	C	C	C	C			2019	No ages specified; additional criteria for <18 y.o.
WY	N	N	N	N				
American Samoa	N	N	N	N				
Mariana Islands	N	N	N	N				
Guam	N	N	N	N				
Puerto Rico	N	N	E	E				Policy mixed, but coverage being provided
U.S. Virgin Islands	N	N	N	N				

\*Key:  
 C - Covered  
 E - Excluded  
 N - No Coverage Statement

Pl. Trial Ex. 031

PLAINTIFF'S EXHIBIT  
 13





Child, Adolescent, and Adult

Psychiatrist, Author  
& International Public Speaker

Home

NEW BOOK!

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Parent Resources

# Miriam Grossman MD



Pl. Trial Ex. 032

Miriam Grossman MD is a practicing psychiatrist, author, and public speaker. Before gender ideology was on anyone's radar, she warned parents about its falsehoods and dangers in the final chapter of her 2009 book about sexuality education, "You're Teaching My Child WHAT?"

Dr. Grossman's practice currently focuses on gender-confused young people and their parents. She believes that every child is born in the right body. Dr. Grossman has been vocal about the capture of her profession by ideologues, leading to dangerous and experimental treatments on children and betrayal of parents.

The author of four books, Dr. Grossman has been on over 300 radio, news, and television shows, and her work exposing the origin and hazards of the Sexuality and Gender Industry has been translated into eleven languages. She has lectured at the British House of Lords and the United Nations.

Dr. Grossman is featured in Dailly Wire's *What Is A Woman?* and Fox Nation's documentary *The Miseducation of America*. Her recent articles have been published in media outlets such as The Dailly Wire, Breitbart News, The Federalist and City Journal. Dr. Grossman's expert psychiatric opinion is sought for witness testimony and court reports.

Dr. Grossman graduated with honors from Bryn Mawr College and from New York University Medical School. She completed an internship in pediatrics at Beth Israel Hospital in New York City, and a residency in psychiatry at North Shore University Hospital – Cornell University Medical College, followed by a fellowship in child and adolescent psychiatry. Dr. Grossman is board certified in psychiatry and in the sub-specialty of child and adolescent psychiatry.

Contact Dr. Grossman

**Родители и наставници!  
Ова е за ВАС!**

**ВИСТИНАТА ЗА РОДОТ - ДЕЛ 1  
РАЗОТКРИВАЊЕ НА ССО АГЕНДАТА**

**Д-р МИРИАМ ГРОСМАН**

24 јуни 2021 | 19:30  
ЗУМ настан

СА НАС ЗА НАС

Доктор, обучен за родителски и специјализиран за деца, специјализирана во лезбичко, гомосексуелно и транс гендерни области. Ги потпишува сите нејзини научни публикации. (SSO) на есејна осмисла на расно-сексуалните организации.

©2022 by Miriam Grossman MD

Dr. Grossman's work has been published in 11 languages

# Gender Dysphoria

In this chapter, there is one overarching diagnosis of gender dysphoria, with separate developmentally appropriate criteria sets for children and for adolescents and adults. The area of sex and gender is highly controversial and has led to a proliferation of terms whose meanings vary over time and within and between disciplines. An additional source of confusion is that in English “sex” connotes both male/female and sexuality. This chapter employs constructs and terms as they are widely used by clinicians from various disciplines with specialization in this area. In this chapter, *sex* and *sexual* refer to the biological indicators of male and female (understood in the context of reproductive capacity), such as in sex chromosomes, gonads, sex hormones, and nonambiguous internal and external genitalia. Disorders of sex development denote conditions of inborn somatic deviations of the reproductive tract from the norm and/or discrepancies among the biological indicators of male and female. *Cross-sex* hormone treatment denotes the use of feminizing hormones in an individual assigned male at birth based on traditional biological indicators or the use of masculinizing hormones in an individual assigned female at birth.

The need to introduce the term *gender* arose with the realization that for individuals with conflicting or ambiguous biological indicators of sex (i.e., “intersex”), the lived role in society and/or the identification as male or female could not be uniformly associated with or predicted from the biological indicators and, later, that some individuals develop an identity as female or male at variance with their uniform set of classical biological indicators. Thus, *gender* is used to denote the public (and usually legally recognized) lived role as boy or girl, man or woman, but, in contrast to certain social constructionist theories, biological factors are seen as contributing, in interaction with social and psychological factors, to gender development. *Gender assignment* refers to the initial assignment as male or female. This occurs usually at birth and, thereby, yields the “natal gender.” *Gender-atypical* refers to somatic features or behaviors that are not typical (in a statistical sense) of individuals with the same assigned gender in a given society and historical era; for behavior, *gender-nonconforming* is an alternative descriptive term. *Gender reassignment* denotes an official (and usually legal) change of gender. *Gender identity* is a category of social identity and refers to an individual’s identification as male, female, or, occasionally, some category other than male or female. *Gender dysphoria* as a general descriptive term refers to an individual’s affective/cognitive discontent with the assigned gender but is more specifically defined when used as a diagnostic category. *Transgender* refers to the broad spectrum of individuals who transiently or persistently identify with a gender different from their natal gender. *Transsexual* denotes an individual who seeks, or has undergone, a social transition from male to female or female to male, which in many, but not all, cases also involves a somatic transition by cross-sex hormone treatment and genital surgery (*sex reassignment surgery*).

*Gender dysphoria* refers to the distress that may accompany the incongruence between one’s experienced or expressed gender and one’s assigned gender. Although not all individuals will experience distress as a result of such incongruence, many are distressed if the desired physical interventions by means of hormones and/or surgery are not available. The current term is more descriptive than the previous DSM-IV term *gender identity disorder* and focuses on dysphoria as the clinical problem, not identity per se.



## Gender Dysphoria

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### Diagnostic Criteria

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#### Gender Dysphoria in Children

**302.6 (F64.2)**

- A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least six of the following (one of which must be Criterion A1):
1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender).
  2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.
  3. A strong preference for cross-gender roles in make-believe play or fantasy play.
  4. A strong preference for the toys, games, or activities stereotypically used or engaged in by the other gender.
  5. A strong preference for playmates of the other gender.
  6. In boys (assigned gender), a strong rejection of typically masculine toys, games, and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities.
  7. A strong dislike of one's sexual anatomy.
  8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.
- B. The condition is associated with clinically significant distress or impairment in social, school, or other important areas of functioning.

*Specify if:*

**With a disorder of sex development** (e.g., a congenital adrenogenital disorder such as 255.2 [E25.0] congenital adrenal hyperplasia or 259.50 [E34.50] androgen insensitivity syndrome).

**Coding note:** Code the disorder of sex development as well as gender dysphoria.

#### Gender Dysphoria in Adolescents and Adults

**302.85 (F64.1)**

- A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:
1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics).
  2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).
  3. A strong desire for the primary and/or secondary sex characteristics of the other gender.
  4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
  5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
  6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).



- B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

*Specify if:*

**With a disorder of sex development** (e.g., a congenital adrenogenital disorder such as 255.2 [E25.0] congenital adrenal hyperplasia or 259.50 [E34.50] androgen insensitivity syndrome).

**Coding note:** Code the disorder of sex development as well as gender dysphoria.

*Specify if:*

**Posttransition:** The individual has transitioned to full-time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one cross-sex medical procedure or treatment regimen—namely, regular cross-sex hormone treatment or gender reassignment surgery confirming the desired gender (e.g., penectomy, vaginoplasty in a natal male; mastectomy or phalloplasty in a natal female).

## Specifiers

The posttransition specifier may be used in the context of continuing treatment procedures that serve to support the new gender assignment.

## Diagnostic Features

Individuals with gender dysphoria have a marked incongruence between the gender they have been assigned to (usually at birth, referred to as *natal gender*) and their experienced/expressed gender. This discrepancy is the core component of the diagnosis. There must also be evidence of distress about this incongruence. Experienced gender may include alternative gender identities beyond binary stereotypes. Consequently, the distress is not limited to a desire to simply be of the other gender, but may include a desire to be of an alternative gender, provided that it differs from the individual's assigned gender.

Gender dysphoria manifests itself differently in different age groups. Prepubertal natal girls with gender dysphoria may express the wish to be a boy, assert they are a boy, or assert they will grow up to be a man. They prefer boys' clothing and hairstyles, are often perceived by strangers as boys, and may ask to be called by a boy's name. Usually, they display intense negative reactions to parental attempts to have them wear dresses or other feminine attire. Some may refuse to attend school or social events where such clothes are required. These girls may demonstrate marked cross-gender identification in role-playing, dreams, and fantasies. Contact sports, rough-and-tumble play, traditional boyhood games, and boys as playmates are most often preferred. They show little interest in stereotypically feminine toys (e.g., dolls) or activities (e.g., feminine dress-up or role-play). Occasionally, they refuse to urinate in a sitting position. Some natal girls may express a desire to have a penis or claim to have a penis or that they will grow one when older. They may also state that they do not want to develop breasts or menstruate.

Prepubertal natal boys with gender dysphoria may express the wish to be a girl or assert they are a girl or that they will grow up to be a woman. They have a preference for dressing in girls' or women's clothes or may improvise clothing from available materials (e.g., using towels, aprons, and scarves for long hair or skirts). These children may role-play female figures (e.g., playing "mother") and often are intensely interested in female fantasy figures. Traditional feminine activities, stereotypical games, and pastimes (e.g., "playing house"; drawing feminine pictures; watching television or videos of favorite female characters) are most often preferred. Stereotypical female-type dolls (e.g., Barbie) are often favorite toys, and girls are their preferred playmates. They avoid rough-and-tumble play and competitive sports and have little interest in stereotypically masculine toys (e.g., cars, trucks). Some may pretend not to have a penis and insist on sitting to urinate. More

rarely, they may state that they find their penis or testes disgusting, that they wish them removed, or that they have, or wish to have, a vagina.

In young adolescents with gender dysphoria, clinical features may resemble those of children or adults with the condition, depending on developmental level. As secondary sex characteristics of young adolescents are not yet fully developed, these individuals may not state dislike of them, but they are concerned about imminent physical changes.

In adults with gender dysphoria, the discrepancy between experienced gender and physical sex characteristics is often, but not always, accompanied by a desire to be rid of primary and/or secondary sex characteristics and/or a strong desire to acquire some primary and/or secondary sex characteristics of the other gender. To varying degrees, adults with gender dysphoria may adopt the behavior, clothing, and mannerisms of the experienced gender. They feel uncomfortable being regarded by others, or functioning in society, as members of their assigned gender. Some adults may have a strong desire to be of a different gender and treated as such, and they may have an inner certainty to feel and respond as the experienced gender without seeking medical treatment to alter body characteristics. They may find other ways to resolve the incongruence between experienced/expressed and assigned gender by partially living in the desired role or by adopting a gender role neither conventionally male nor conventionally female.

## **Associated Features Supporting Diagnosis**

When visible signs of puberty develop, natal boys may shave their legs at the first signs of hair growth. They sometimes bind their genitals to make erections less visible. Girls may bind their breasts, walk with a stoop, or use loose sweaters to make breasts less visible. Increasingly, adolescents request, or may obtain without medical prescription and supervision, hormonal suppressors (“blockers”) of gonadal steroids (e.g., gonadotropin-releasing hormone [GnRH] analog, spironolactone). Clinically referred adolescents often want hormone treatment and many also wish for gender reassignment surgery. Adolescents living in an accepting environment may openly express the desire to be and be treated as the experienced gender and dress partly or completely as the experienced gender, have a hairstyle typical of the experienced gender, preferentially seek friendships with peers of the other gender, and/or adopt a new first name consistent with the experienced gender. Older adolescents, when sexually active, usually do not show or allow partners to touch their sexual organs. For adults with an aversion toward their genitals, sexual activity is constrained by the preference that their genitals not be seen or touched by their partners. Some adults may seek hormone treatment (sometimes without medical prescription and supervision) and gender reassignment surgery. Others are satisfied with either hormone treatment or surgery alone.

Adolescents and adults with gender dysphoria before gender reassignment are at increased risk for suicidal ideation, suicide attempts, and suicides. After gender reassignment, adjustment may vary, and suicide risk may persist.

## **Prevalence**

For natal adult males, prevalence ranges from 0.005% to 0.014%, and for natal females, from 0.002% to 0.003%. Since not all adults seeking hormone treatment and surgical reassignment attend specialty clinics, these rates are likely modest underestimates. Sex differences in rate of referrals to specialty clinics vary by age group. In children, sex ratios of natal boys to girls range from 2:1 to 4.5:1. In adolescents, the sex ratio is close to parity; in adults, the sex ratio favors natal males, with ratios ranging from 1:1 to 6.1:1. In two countries, the sex ratio appears to favor natal females (Japan: 2.2:1; Poland: 3.4:1).

## **Development and Course**

Because expression of gender dysphoria varies with age, there are separate criteria sets for children versus adolescents and adults. Criteria for children are defined in a more con-

crete, behavioral manner than those for adolescents and adults. Many of the core criteria draw on well-documented behavioral gender differences between typically developing boys and girls. Young children are less likely than older children, adolescents, and adults to express extreme and persistent anatomic dysphoria. In adolescents and adults, incongruence between experienced gender and somatic sex is a central feature of the diagnosis. Factors related to distress and impairment also vary with age. A very young child may show signs of distress (e.g., intense crying) only when parents tell the child that he or she is “really” not a member of the other gender but only “desires” to be. Distress may not be manifest in social environments supportive of the child’s desire to live in the role of the other gender and may emerge only if the desire is interfered with. In adolescents and adults, distress may manifest because of strong incongruence between experienced gender and somatic sex. Such distress may, however, be mitigated by supportive environments and knowledge that biomedical treatments exist to reduce incongruence. Impairment (e.g., school refusal, development of depression, anxiety, and substance abuse) may be a consequence of gender dysphoria.

**Gender dysphoria without a disorder of sex development.** For clinic-referred children, onset of cross-gender behaviors is usually between ages 2 and 4 years. This corresponds to the developmental time period in which most typically developing children begin expressing gendered behaviors and interests. For some preschool-age children, both pervasive cross-gender behaviors and the expressed desire to be the other gender may be present, or, more rarely, labeling oneself as a member of the other gender may occur. In some cases, the expressed desire to be the other gender appears later, usually at entry into elementary school. A small minority of children express discomfort with their sexual anatomy or will state the desire to have a sexual anatomy corresponding to the experienced gender (“anatomic dysphoria”). Expressions of anatomic dysphoria become more common as children with gender dysphoria approach and anticipate puberty.

Rates of persistence of gender dysphoria from childhood into adolescence or adulthood vary. In natal males, persistence has ranged from 2.2% to 30%. In natal females, persistence has ranged from 12% to 50%. Persistence of gender dysphoria is modestly correlated with dimensional measures of severity ascertained at the time of a childhood baseline assessment. In one sample of natal males, lower socioeconomic background was also modestly correlated with persistence. It is unclear if particular therapeutic approaches to gender dysphoria in children are related to rates of long-term persistence. Extant follow-up samples consisted of children receiving no formal therapeutic intervention or receiving therapeutic interventions of various types, ranging from active efforts to reduce gender dysphoria to a more neutral, “watchful waiting” approach. It is unclear if children “encouraged” or supported to live socially in the desired gender will show higher rates of persistence, since such children have not yet been followed longitudinally in a systematic manner. For both natal male and female children showing persistence, almost all are sexually attracted to individuals of their natal sex. For natal male children whose gender dysphoria does not persist, the majority are *androphilic* (sexually attracted to males) and often self-identify as gay or homosexual (ranging from 63% to 100%). In natal female children whose gender dysphoria does not persist, the percentage who are *gynephilic* (sexually attracted to females) and self-identify as lesbian is lower (ranging from 32% to 50%).

In both adolescent and adult natal males, there are two broad trajectories for development of gender dysphoria: early onset and late onset. *Early-onset gender dysphoria* starts in childhood and continues into adolescence and adulthood; or, there is an intermittent period in which the gender dysphoria desists and these individuals self-identify as gay or homosexual, followed by recurrence of gender dysphoria. *Late-onset gender dysphoria* occurs around puberty or much later in life. Some of these individuals report having had a desire to be of the other gender in childhood that was not expressed verbally to others. Others do not recall any signs of childhood gender dysphoria. For adolescent males with late-onset gender dysphoria, parents often report surprise because they did not see signs of gender



dysphoria during childhood. Expressions of anatomic dysphoria are more common and salient in adolescents and adults once secondary sex characteristics have developed.

Adolescent and adult natal males with early-onset gender dysphoria are almost always sexually attracted to men (androphilic). Adolescents and adults with late-onset gender dysphoria frequently engage in transvestic behavior with sexual excitement. The majority of these individuals are gynephilic or sexually attracted to other posttransition natal males with late-onset gender dysphoria. A substantial percentage of adult males with late-onset gender dysphoria cohabit with or are married to natal females. After gender transition, many self-identify as lesbian. Among adult natal males with gender dysphoria, the early-onset group seeks out clinical care for hormone treatment and reassignment surgery at an earlier age than does the late-onset group. The late-onset group may have more fluctuations in the degree of gender dysphoria and be more ambivalent about and less likely satisfied after gender reassignment surgery.

In both adolescent and adult natal females, the most common course is the early-onset form of gender dysphoria. The late-onset form is much less common in natal females compared with natal males. As in natal males with gender dysphoria, there may have been a period in which the gender dysphoria desisted and these individuals self-identified as lesbian; however, with recurrence of gender dysphoria, clinical consultation is sought, often with the desire for hormone treatment and reassignment surgery. Parents of natal adolescent females with the late-onset form also report surprise, as no signs of childhood gender dysphoria were evident. Expressions of anatomic dysphoria are much more common and salient in adolescents and adults than in children.

Adolescent and adult natal females with early-onset gender dysphoria are almost always gynephilic. Adolescents and adults with the late-onset form of gender dysphoria are usually androphilic and after gender transition self-identify as gay men. Natal females with the late-onset form do not have co-occurring transvestic behavior with sexual excitement.

**Gender dysphoria in association with a disorder of sex development.** Most individuals with a disorder of sex development who develop gender dysphoria have already come to medical attention at an early age. For many, starting at birth, issues of gender assignment were raised by physicians and parents. Moreover, as infertility is quite common for this group, physicians are more willing to perform cross-sex hormone treatments and genital surgery before adulthood.

Disorders of sex development in general are frequently associated with gender-atypical behavior starting in early childhood. However, in the majority of cases, this does not lead to gender dysphoria. As individuals with a disorder of sex development become aware of their medical history and condition, many experience uncertainty about their gender, as opposed to developing a firm conviction that they are another gender. However, most do not progress to gender transition. Gender dysphoria and gender transition may vary considerably as a function of a disorder of sex development, its severity, and assigned gender.

## **Risk and Prognostic Factors**

**Temperamental.** For individuals with gender dysphoria without a disorder of sex development, atypical gender behavior among individuals with early-onset gender dysphoria develops in early preschool age, and it is possible that a high degree of atypicality makes the development of gender dysphoria and its persistence into adolescence and adulthood more likely.

**Environmental.** Among individuals with gender dysphoria without a disorder of sex development, males with gender dysphoria (in both childhood and adolescence) more commonly have older brothers than do males without the condition. Additional predisposing

factors under consideration, especially in individuals with late-onset gender dysphoria (adolescence, adulthood), include habitual fetishistic transvestism developing into autogynephilia (i.e., sexual arousal associated with the thought or image of oneself as a woman) and other forms of more general social, psychological, or developmental problems.

**Genetic and physiological.** For individuals with gender dysphoria without a disorder of sex development, some genetic contribution is suggested by evidence for (weak) familiarity of transsexualism among nontwin siblings, increased concordance for transsexualism in monozygotic compared with dizygotic same-sex twins, and some degree of heritability of gender dysphoria. As to endocrine findings, no endogenous systemic abnormalities in sex-hormone levels have been found in 46,XY individuals, whereas there appear to be increased androgen levels (in the range found in hirsute women but far below normal male levels) in 46,XX individuals. Overall, current evidence is insufficient to label gender dysphoria without a disorder of sex development as a form of intersexuality limited to the central nervous system.

In gender dysphoria associated with a disorder of sex development, the likelihood of later gender dysphoria is increased if prenatal production and utilization (via receptor sensitivity) of androgens are grossly atypical relative to what is usually seen in individuals with the same assigned gender. Examples include 46,XY individuals with a history of normal male prenatal hormone milieu but inborn nonhormonal genital defects (as in cloacal bladder exstrophy or penile agenesis) and who have been assigned to the female gender. The likelihood of gender dysphoria is further enhanced by additional, prolonged, highly gender-atypical postnatal androgen exposure with somatic virilization as may occur in female-raised and noncastrated 46,XY individuals with 5-alpha reductase-2 deficiency or 17-beta-hydroxysteroid dehydrogenase-3 deficiency or in female-raised 46,XX individuals with classical congenital adrenal hyperplasia with prolonged periods of non-adherence to glucocorticoid replacement therapy. However, the prenatal androgen milieu is more closely related to gendered behavior than to gender identity. Many individuals with disorders of sex development and markedly gender-atypical behavior do not develop gender dysphoria. Thus, gender-atypical behavior by itself should not be interpreted as an indicator of current or future gender dysphoria. There appears to be a higher rate of gender dysphoria and patient-initiated gender change from assigned female to male than from assigned male to female in 46,XY individuals with a disorder of sex development.

## **Culture-Related Diagnostic Issues**

Individuals with gender dysphoria have been reported across many countries and cultures. The equivalent of gender dysphoria has also been reported in individuals living in cultures with institutionalized gender categories other than male or female. It is unclear whether with these individuals the diagnostic criteria for gender dysphoria would be met.

## **Diagnostic Markers**

Individuals with a somatic disorder of sex development show some correlation of final gender identity outcome with the degree of prenatal androgen production and utilization. However, the correlation is not robust enough for the biological factor, where ascertainable, to replace a detailed and comprehensive diagnostic interview evaluation for gender dysphoria.

## **Functional Consequences of Gender Dysphoria**

Preoccupation with cross-gender wishes may develop at all ages after the first 2–3 years of childhood and often interfere with daily activities. In older children, failure to develop age-typical same-sex peer relationships and skills may lead to isolation from peer groups and to distress. Some children may refuse to attend school because of teasing and harass-



ment or pressure to dress in attire associated with their assigned sex. Also in adolescents and adults, preoccupation with cross-gender wishes often interferes with daily activities. Relationship difficulties, including sexual relationship problems, are common, and functioning at school or at work may be impaired. Gender dysphoria, along with atypical gender expression, is associated with high levels of stigmatization, discrimination, and victimization, leading to negative self-concept, increased rates of mental disorder comorbidity, school dropout, and economic marginalization, including unemployment, with attendant social and mental health risks, especially in individuals from resource-poor family backgrounds. In addition, these individuals' access to health services and mental health services may be impeded by structural barriers, such as institutional discomfort or inexperience in working with this patient population.

## Differential Diagnosis

**Nonconformity to gender roles.** Gender dysphoria should be distinguished from simple nonconformity to stereotypical gender role behavior by the strong desire to be of another gender than the assigned one and by the extent and pervasiveness of gender-variant activities and interests. The diagnosis is not meant to merely describe nonconformity to stereotypical gender role behavior (e.g., "tomboyism" in girls, "girly-boy" behavior in boys, occasional cross-dressing in adult men). Given the increased openness of atypical gender expressions by individuals across the entire range of the transgender spectrum, it is important that the clinical diagnosis be limited to those individuals whose distress and impairment meet the specified criteria.

**Transvestic disorder.** Transvestic disorder occurs in heterosexual (or bisexual) adolescent and adult males (rarely in females) for whom cross-dressing behavior generates sexual excitement and causes distress and/or impairment without drawing their primary gender into question. It is occasionally accompanied by gender dysphoria. An individual with transvestic disorder who also has clinically significant gender dysphoria can be given both diagnoses. In many cases of late-onset gender dysphoria in gynephilic natal males, transvestic behavior with sexual excitement is a precursor.

**Body dysmorphic disorder.** An individual with body dysmorphic disorder focuses on the alteration or removal of a specific body part because it is perceived as abnormally formed, not because it represents a repudiated assigned gender. When an individual's presentation meets criteria for both gender dysphoria and body dysmorphic disorder, both diagnoses can be given. Individuals wishing to have a healthy limb amputated (termed by some *body integrity identity disorder*) because it makes them feel more "complete" usually do not wish to change gender, but rather desire to live as an amputee or a disabled person.

**Schizophrenia and other psychotic disorders.** In schizophrenia, there may rarely be delusions of belonging to some other gender. In the absence of psychotic symptoms, insistence by an individual with gender dysphoria that he or she is of some other gender is not considered a delusion. Schizophrenia (or other psychotic disorders) and gender dysphoria may co-occur.

**Other clinical presentations.** Some individuals with an emasculation desire who develop an alternative, nonmale/nonfemale gender identity do have a presentation that meets criteria for gender dysphoria. However, some males seek castration and/or penectomy for aesthetic reasons or to remove psychological effects of androgens without changing male identity; in these cases, the criteria for gender dysphoria are not met.

## Comorbidity

Clinically referred children with gender dysphoria show elevated levels of emotional and behavioral problems—most commonly, anxiety, disruptive and impulse-control, and de-

pressive disorders. In prepubertal children, increasing age is associated with having more behavioral or emotional problems; this is related to the increasing non-acceptance of gender-variant behavior by others. In older children, gender-variant behavior often leads to peer ostracism, which may lead to more behavioral problems. The prevalence of mental health problems differs among cultures; these differences may also be related to differences in attitudes toward gender variance in children. However, also in some non-Western cultures, anxiety has been found to be relatively common in individuals with gender dysphoria, even in cultures with accepting attitudes toward gender-variant behavior. Autism spectrum disorder is more prevalent in clinically referred children with gender dysphoria than in the general population. Clinically referred adolescents with gender dysphoria appear to have comorbid mental disorders, with anxiety and depressive disorders being the most common. As in children, autism spectrum disorder is more prevalent in clinically referred adolescents with gender dysphoria than in the general population. Clinically referred adults with gender dysphoria may have coexisting mental health problems, most commonly anxiety and depressive disorders.

## Other Specified Gender Dysphoria

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**302.6 (F64.8)**

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This category applies to presentations in which symptoms characteristic of gender dysphoria that cause clinically significant distress or impairment in social, occupational, or other important areas of functioning predominate but do not meet the full criteria for gender dysphoria. The other specified gender dysphoria category is used in situations in which the clinician chooses to communicate the specific reason that the presentation does not meet the criteria for gender dysphoria. This is done by recording “other specified gender dysphoria” followed by the specific reason (e.g., “brief gender dysphoria”).

An example of a presentation that can be specified using the “other specified” designation is the following:

**The current disturbance meets symptom criteria for gender dysphoria, but the duration is less than 6 months.**

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## Unspecified Gender Dysphoria

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**302.6 (F64.9)**

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This category applies to presentations in which symptoms characteristic of gender dysphoria that cause clinically significant distress or impairment in social, occupational, or other important areas of functioning predominate but do not meet the full criteria for gender dysphoria. The unspecified gender dysphoria category is used in situations in which the clinician chooses *not* to specify the reason that the criteria are not met for gender dysphoria, and includes presentations in which there is insufficient information to make a more specific diagnosis.

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