American College of Radiology ACR Appropriateness Criteria® Antenatal Hydronephrosis-Infant

Variant: 1 Antenatal diagnosis of hydronephrosis. Initial neonatal imaging.

| Procedure | Appropriateness Category | Peds Relative Radiation Level |
|---|--------------------------|-------------------------------|
| US kidneys and bladder | Usually Appropriate | 0 |
| Voiding urosonography | Usually Not Appropriate | 0 |
| Fluoroscopy voiding cystourethrography | Usually Not Appropriate | € € |
| MRI abdomen and pelvis with IV contrast | Usually Not Appropriate | 0 |
| MRI abdomen and pelvis without and with IV contrast | Usually Not Appropriate | 0 |
| MRI abdomen and pelvis without IV contrast | Usually Not Appropriate | 0 |
| Nuclear medicine cystography | Usually Not Appropriate | ☆☆ |
| DTPA renal scan | Usually Not Appropriate | ⊗ ⊗ |
| MAG3 renal scan | Usually Not Appropriate | ⊛ ⊛ |

Variant: 2 Antenatal diagnosis of hydronephrosis with normal neonatal ultrasound.

| Procedure | Appropriateness Category | Peds Relative Radiation Level |
|---|--------------------------|-------------------------------|
| US kidneys and bladder follow-up in 1-6 months | Usually Appropriate | 0 |
| Voiding urosonography | Usually Not Appropriate | 0 |
| Fluoroscopy voiding cystourethrography | Usually Not Appropriate | ⊗ ⊗ |
| MRI abdomen and pelvis with IV contrast | Usually Not Appropriate | 0 |
| MRI abdomen and pelvis without and with IV contrast | Usually Not Appropriate | 0 |
| MRI abdomen and pelvis without IV contrast | Usually Not Appropriate | 0 |
| Nuclear medicine cystography | Usually Not Appropriate | ⊗ ⊗ |
| DTPA renal scan | Usually Not Appropriate | ⊗ ⊗ |
| MAG3 renal scan | Usually Not Appropriate | ⊗ ⊗ |

<u>Variant: 3</u> Antenatal diagnosis of hydronephrosis with isolated mild (SFU grade 1 and 2 or APRPD less than 15 mm) hydronephrosis on initial neonatal ultrasound.

| Procedure | Appropriateness Category | Peds Relative Radiation Level |
|---|--------------------------|-------------------------------|
| US kidneys and bladder follow-up in 1-6 months | Usually Appropriate | 0 |
| Voiding urosonography | May Be Appropriate | 0 |
| Fluoroscopy voiding cystourethrography | May Be Appropriate | ⊗ ⊗ |
| MRI abdomen and pelvis with IV contrast | Usually Not Appropriate | 0 |
| MRI abdomen and pelvis without and with IV contrast | Usually Not Appropriate | 0 |
| MRI abdomen and pelvis without IV contrast | Usually Not Appropriate | 0 |
| Nuclear medicine cystography | Usually Not Appropriate | € € |
| DTPA renal scan | Usually Not Appropriate | ⊛ ⊛ |
| MAG3 renal scan | Usually Not Appropriate | ⊛ ⊛ |

<u>Variant: 4</u> Male. Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound, or hydronephrosis associated with parenchymal abnormalities, hydroureter, bladder wall

thickening, or posterior urethral dilation.

| Procedure | Appropriateness Category | Peds Relative Radiation Level |
|---|--------------------------|-------------------------------|
| US kidneys and bladder follow-up in 1-6 months | Usually Appropriate | 0 |
| Fluoroscopy voiding cystourethrography | Usually Appropriate | ⊗ ⊗ |
| MAG3 renal scan | Usually Appropriate | ⊗ ⊗ |
| Voiding urosonography | Usually Not Appropriate | 0 |
| MRI abdomen and pelvis with IV contrast | Usually Not Appropriate | 0 |
| MRI abdomen and pelvis without and with IV contrast | Usually Not Appropriate | 0 |
| MRI abdomen and pelvis without IV contrast | Usually Not Appropriate | 0 |
| Nuclear medicine cystography | Usually Not Appropriate | ⊗ ⊗ |
| DTPA renal scan | Usually Not Appropriate | ∵ ∵ |

<u>Variant: 5</u> Female. Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound, or hydronephrosis associated with parenchymal abnormalities, hydroureter, bladder wall thickening.

| Procedure | Appropriateness Category | Peds Relative Radiation Level |
|---|-----------------------------------|-------------------------------|
| US kidneys and bladder follow-up in 1-6 months | Usually Appropriate | 0 |
| Voiding urosonography | Usually Appropriate | 0 |
| Fluoroscopy voiding cystourethrography | Usually Appropriate | ⊗ ⊗ |
| MAG3 renal scan | Usually Appropriate | ��� |
| Nuclear medicine cystography | May Be Appropriate (Disagreement) | ⊗ ⊗ |
| MRI abdomen and pelvis with IV contrast | Usually Not Appropriate | 0 |
| MRI abdomen and pelvis without and with IV contrast | Usually Not Appropriate | 0 |
| MRI abdomen and pelvis without IV contrast | Usually Not Appropriate | 0 |
| DTPA renal scan | Usually Not Appropriate | ∵ ∵ |

<u>Variant: 6</u> Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound and no evidence of reflux on VCUG.

| Procedure | Appropriateness Category | Peds Relative Radiation Level |
|---|-----------------------------------|-------------------------------|
| US kidneys and bladder follow-up in 1-6 months | Usually Appropriate | 0 |
| MAG3 renal scan | Usually Appropriate | ⊗ ⊗ ⊗ |
| MRI abdomen and pelvis with IV contrast | May Be Appropriate (Disagreement) | 0 |
| MRI abdomen and pelvis without and with IV contrast | May Be Appropriate | 0 |
| DTPA renal scan | May Be Appropriate | ⊗ ⊗ ⊗ |
| MRI abdomen and pelvis without IV contrast | Usually Not Appropriate | 0 |

Panel Members

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Summary of Literature Review

Introduction/Background

Antenatal hydronephrosis is the most frequent urinary tract anomaly detected on prenatal screening by ultrasonography (US). Antenatal hydronephrosis occurs approximately twice as often in males as in females [1-4]. With an estimated 4 million births per year in the United States, up to 80,000 fetal studies may detect antenatal hydronephrosis. Most antenatal hydronephrosis is transient with little long-term significance [5-8]. Few children with antenatal hydronephrosis, including some with ureteropelvic junction obstruction (UPJO), vesicoureteral reflux (VUR), and primary megaureter will have significant obstruction, develop symptoms or complications, which requires surgical intervention. Some male children will be diagnosed with more serious conditions, such as posterior urethral valves (PUV), which may require intervention. Early detection and treatment of obstructive uropathy is necessary to mitigate the potential morbidity from loss of renal function.

During prenatal evaluation, most antenatal hydronephrosis is mild, and the cause cannot always be determined with certainty. As a result, postnatal evaluation of these children is frequently performed. In an effort to standardize grading of antenatal hydronephrosis, the Society for Fetal Urology (SFU) introduced a five point grading system in 1988, based on degree of pelvic and calyceal dilation and the thickness of the parenchyma overlying the calices [9]. Since its introduction, the SFU grading system has become the most widely used method to grade pediatric hydronephrosis [10]. Subsequently, several alternative classification schemes have also been devised [3,4,11,12]. Adherence to standardized reporting models is not well adopted according to a recent survey of pediatric radiologists [13,14], In order to increase standardization of reporting and care, a consensus group from many separate organizations recommended adoption of the urinary tract dilation (UTD) classification system which incorporates prenatal and postnatal imaging findings based on: 1) anterior-posterior renal pelvic diameter (APRPD); 2) calyceal dilation with distinction between central and peripheral calyceal dilation postnatally; 3) renal parenchymal thickness; 4) renal parenchymal appearance; 5) bladder abnormalities; and 6) ureteral abnormalities. For antenatal studies, the seventh US finding to report is the quantity of amniotic fluid [3]. This recently proposed grading classification system, as with any system, will require extensive evaluation to assess and confirm its usefulness in predicting clinical outcomes [3].

For the purposes of the current evaluation, degree of hydronephrosis is based on the SFU grading. The SFU system has been in use for a longer period of time and has good inter-rater reliability [3,15,16]. There are studies that have shown increased accuracy of hydronephrosis grading system if APRPD is measured [17,18]. We therefore have included an APRPD of >15 mm on postnatal imaging as a sign of severe hydronephrosis. Over time, the UTD classification system may predominate, but at present, familiarity with the SFU system is more widespread. Inclusion of the APRPD >15 mm conforms to the intermediate- to high-risk urinary tract dilation stratification [3].

Initial Imaging Definition

Initial imaging is defined as imaging at the beginning of the care episode for the medical condition defined by the variant. More than one procedure can be considered usually appropriate in the initial imaging evaluation when:

• There are procedures that are equivalent alternatives (i.e., only one procedure will be ordered to provide the clinical information to effectively manage the patient's care)

OR

• There are complementary procedures (i.e., more than one procedure is ordered as a set or simultaneously wherein each procedure provides unique clinical information to effectively manage the patient's care).

Discussion of Procedures by Variant

Variant 1: Antenatal diagnosis of hydronephrosis. Initial neonatal imaging.

Variant 1: Antenatal diagnosis of hydronephrosis. Initial neonatal imaging. A. US Kidneys and Bladder

US in the immediate postnatal period evaluates for the presence and severity of underlying urologic abnormalities and therefore has a role in guiding management [3,6,12,19-25]. Because of the relative low urine production in newborns, initial imaging should be delayed at least 48 to 72 hours after birth [3,26-29]. Exceptions include newborns with severe, bilateral hydronephrosis and bladder abnormalities, oligohydramnios, or situations in which follow-up studies may be difficult to obtain. In these infants, earlier imaging is indicated [20,27,29,30].

Variant 1: Antenatal diagnosis of hydronephrosis. Initial neonatal imaging. B. Fluoroscopic Voiding Cystourethrography

There is controversy regarding whether all children with antenatal hydronephrosis should undergo voiding cystourethrography (VCUG). A meta-analysis by the American Urology Association found that, on average, approximately 16% of neonates and infants with antenatal hydronephrosis will have VUR. The incidence of VUR was independent of degree of antenatal hydronephrosis, and a quarter of these were found to have no hydronephrosis on postnatal US [31]. There is disagreement over whether this VUR is clinically significant and therefore over the need for diagnosis. Some authors advocate VCUG for all infants with antenatal hydronephrosis, to guide treatment with prophylactic antibiotics [20,27,32,33]. However, currently, most authors (including the 2010 SFU consensus statement) recommend against routine VCUG for antenatal hydronephrosis [2,12,29,34,35]. This is largely because the benefit of prophylactic antibiotics in children with urinary tract infection (UTI) has not been clearly demonstrated and remains controversial. Some studies have suggested that prophylactic antibiotics may be beneficial in patients with VUR [36-38]. The efficacy of prophylactic antibiotics in preventing UTIs or renal damage in patients with antenatal hydronephrosis, with or without VUR, is difficult to determine because of variability in methods and results [39]. In addition, most of the VUR spontaneously resolves [40]. One of the potential risks of VCUG is iatrogenic UTI. This was reported in about 2% of VCUG studies performed for evaluation of antenatal hydronephrosis [39].

Variant 1: Antenatal diagnosis of hydronephrosis. Initial neonatal imaging. C. Voiding Urosonography

Multiple recent investigations evaluating real-time contrast-enhanced US techniques have demonstrated a high degree of diagnostic accuracy, and some demonstrated increased sensitivity as compared to fluoroscopic VCUG in the detection of VUR [41-45]. The main potential disadvantage of voiding urosonography is a lower anatomical detail of the bladder and urethra,

and therefore it should not be used as the first study for male patients. Therefore, arguments for and against using voiding urosonography are similar to that of VCUG with the exception of male patients.

Variant 1: Antenatal diagnosis of hydronephrosis. Initial neonatal imaging. D. Nuclear Medicine Cystography

Some studies have suggested equal sensitivity for Tc-99m pertechnetate radionuclide cystography and VCUG [46], whereas others have indicated that radionuclide cystography has improved sensitivity for VUR in infants up to 1 year of age [47]. The main disadvantage of radionuclide cystography is that it does not provide anatomical details of the bladder and urethra and therefore should not be used as the first study for male patients. Therefore, arguments for and against using radionuclide cystography are similar to that of VCUG with the exception of male patients.

Variant 1: Antenatal diagnosis of hydronephrosis. Initial neonatal imaging. E. DTPA Renal Scan

There is no relevant literature to support the routine use of Tc-99m diethylenetriamine pentaacetic acid (DTPA) renal scan in the initial postnatal evaluation of antenatal hydronephrosis.

Variant 1: Antenatal diagnosis of hydronephrosis. Initial neonatal imaging. F. MAG3 Renal Scan

There is no relevant literature to support the routine use of Tc-99m mercaptoacetyltriglycine (MAG3) diuretic renal scan in the initial postnatal evaluation of antenatal hydronephrosis.

Variant 1: Antenatal diagnosis of hydronephrosis. Initial neonatal imaging. G. MRI Abdomen and Pelvis

There is no relevant literature to support the routine use of MR urography (MRU) in the initial postnatal evaluation of antenatal hydronephrosis.

Variant 2: Antenatal diagnosis of hydronephrosis with normal neonatal ultrasound.

Variant 2: Antenatal diagnosis of hydronephrosis with normal neonatal ultrasound. A. US Kidneys and Bladder Follow-Up in 1–6 Months

Lower urinary production in the immediate postnatal period can mask urinary tract abnormalities. In a study by Aksu et al [26], 45% of initially normal postnatal studies had abnormal findings on repeat imaging, including UPJO, VUR, and ureterovesical junction obstruction. Even with a normal initial postnatal US, follow-up studies are recommended for exclusion of later-developing hydronephrosis [3,30,48]. Given the late presentation of some urinary tract abnormalities, a repeat US is recommended in 1 to 6 months [4,5,49,50].

Variant 2: Antenatal diagnosis of hydronephrosis with normal neonatal ultrasound. B. Fluoroscopic Voiding Cystourethrography

There is controversy regarding whether all children with antenatal hydronephrosis should undergo VCUG. A meta-analysis by the American Urology Association found that on average, approximately 16% of neonates and infants with antenatal hydronephrosis will have VUR. The incidence of VUR was independent of degree of antenatal hydronephrosis, and a quarter of these were found to have no hydronephrosis on postnatal US [31]. There is disagreement over whether this VUR is clinically significant and therefore over the need for diagnosis. Some authors advocate VCUG for all infants with antenatal hydronephrosis, to guide treatment with prophylactic antibiotics [20,27,32,33]. However, currently, most authors (including the 2010 SFU consensus statement)

recommend against routine VCUG for antenatal hydronephrosis [2,12,29,34,35]. This is largely because the benefit of prophylactic antibiotic in children with UTI has not been clearly demonstrated [36]. The efficacy of prophylactic antibiotics in preventing UTIs or renal damage in patients with antenatal hydronephrosis, with or without VUR, is difficult to determine because of variability in methods and results [39]. In addition, most of the VUR spontaneously resolves [40]. One of the potential risks of VCUG is iatrogenic UTI. This was reported in about 2% of VCUG studies performed for evaluation of antenatal hydronephrosis [39].

Variant 2: Antenatal diagnosis of hydronephrosis with normal neonatal ultrasound. C. Voiding Urosonography

Multiple recent investigations evaluating real-time contrast-enhanced US techniques have demonstrated a high degree of diagnostic accuracy, and some demonstrated increased sensitivity as compared to fluoroscopic VCUG in the detection of VUR [41-45]. The main potential disadvantage of voiding urosonography is a lower anatomical detail of the bladder and urethra, and therefore it should not be used as the first study for male patients. Therefore, arguments for and against using voiding urosonography are similar to that of VCUG with the exception of male patients.

Variant 2: Antenatal diagnosis of hydronephrosis with normal neonatal ultrasound. D. Nuclear Medicine Cystography

Some studies have suggested equal sensitivity for Tc-99m pertechnetate radionuclide cystography and VCUG [46], whereas others have indicated that radionuclide cystography has improved sensitivity for VUR in infants up to 1 year of age [47]. The main disadvantage of radionuclide cystography is that it does not provide anatomical details of the bladder and urethra and therefore should not be used as the first study for male patients. Therefore, arguments for and against using radionuclide cystography are similar to that of VCUG with the exception of male patients.

Variant 2: Antenatal diagnosis of hydronephrosis with normal neonatal ultrasound. E. DTPA Renal Scan

There is no relevant literature to support the routine use of Tc-99m DTPA renal scan in the setting of a normal neonatal US.

Variant 2: Antenatal diagnosis of hydronephrosis with normal neonatal ultrasound. F. MAG3 Renal Scan

There is no relevant literature to support the routine use of Tc-99m MAG3 diuretic renal scan in the setting of a normal neonatal US.

Variant 2: Antenatal diagnosis of hydronephrosis with normal neonatal ultrasound. G. MRI Abdomen and Pelvis

There is no relevant literature to support the routine use of MRU in the in the setting of a normal neonatal US.

Variant 3: Antenatal diagnosis of hydronephrosis with isolated mild (SFU grade 1 and 2 or APRPD less than 15 mm) hydronephrosis on initial neonatal ultrasound.

Variant 3: Antenatal diagnosis of hydronephrosis with isolated mild (SFU grade 1 and 2 or APRPD less than 15 mm) hydronephrosis on initial neonatal ultrasound. A. US Kidneys and Bladder Follow-Up in 1–6 Months

Studies have confirmed the possibility of development of significant urinary tract conditions with

even mild hydronephrosis on prenatal and initial postnatal imaging [8]. Therefore, mild findings on postnatal renal US do not exclude a urinary tract abnormality. Given the late development of some urinary tract abnormalities, a repeat US is recommended by some authors suggesting this examination be performed at 1 to 6 months [4,5,49,50]. However, in children with mild hydronephrosis, there has shown to be a low risk of underlying anatomic abnormality, including UPJO [10].

Variant 3: Antenatal diagnosis of hydronephrosis with isolated mild (SFU grade 1 and 2 or APRPD less than 15 mm) hydronephrosis on initial neonatal ultrasound. B. Fluoroscopic Voiding Cystourethrography

There is controversy regarding whether all children with antenatal hydronephrosis should undergo VCUG. A meta-analysis by the American Urology Association found that, on average, approximately 16% of neonates and infants with antenatal hydronephrosis will have VUR. The incidence of VUR was independent of degree of antenatal hydronephrosis, and a quarter of these were found to have no hydronephrosis on postnatal US [31]. There is disagreement over whether this VUR is clinically significant and therefore over the need for diagnosis. Some authors advocate VCUG for all infants with antenatal hydronephrosis, to guide treatment with prophylactic antibiotics [20,27,32,33]. However, currently, most authors (including the 2010 SFU consensus statement) recommend against routine VCUG for antenatal hydronephrosis [2,12,29,34,35]. This is largely because the benefit of prophylactic antibiotic in children with UTI has not been clearly demonstrated [36]. The efficacy of prophylactic antibiotics in preventing UTIs or renal damage in patients with antenatal hydronephrosis, with or without VUR, is difficult to determine because of variability in methods and results [39]. In addition, most of the VUR spontaneously resolves [40]. One of the potential risks of VCUG is iatrogenic UTI. This was reported in about 2% of VCUG studies performed for evaluation of antenatal hydronephrosis [39].

Variant 3: Antenatal diagnosis of hydronephrosis with isolated mild (SFU grade 1 and 2 or APRPD less than 15 mm) hydronephrosis on initial neonatal ultrasound. C. Voiding Urosonography

Multiple recent investigations evaluating real-time contrast-enhanced US techniques have demonstrated a high degree of diagnostic accuracy, and some demonstrated increased sensitivity as compared to fluoroscopic VCUG in the detection of VUR [41-45]. The main potential disadvantage of voiding urosonography is a lower anatomical detail of the bladder and urethra, and therefore it should not be used as the first study for male patients. Therefore, arguments for and against using voiding urosonography are similar to that of VCUG with the exception of male patients.

Variant 3: Antenatal diagnosis of hydronephrosis with isolated mild (SFU grade 1 and 2 or APRPD less than 15 mm) hydronephrosis on initial neonatal ultrasound. D. Nuclear Medicine Cystography

Some studies have suggested equal sensitivity for Tc-99m pertechnetate radionuclide cystography and VCUG [46], whereas others have indicated that radionuclide cystography has improved sensitivity for VUR in infants up to 1 year of age [47]. The main disadvantage of radionuclide cystography is that it does not provide anatomical details of the bladder and urethra and therefore should not be used as the first study for male patients. Therefore, arguments for and against using radionuclide cystography are similar to that of VCUG with the exception of male patients.

Variant 3: Antenatal diagnosis of hydronephrosis with isolated mild (SFU grade 1 and 2 or APRPD less than 15 mm) hydronephrosis on initial neonatal ultrasound.

E. DTPA Renal Scan

There is no relevant literature to support the routine use of Tc-99m DTPA renal scan as the first imaging in the evaluation of mild antenatal hydronephrosis, because there is low risk of underlying anatomic abnormality such as UPJO in the setting of mild hydronephrosis.

Variant 3: Antenatal diagnosis of hydronephrosis with isolated mild (SFU grade 1 and 2 or APRPD less than 15 mm) hydronephrosis on initial neonatal ultrasound.

F. MAG3 Renal Scan

There is no relevant literature to support the routine use of Tc-99m MAG3 diuretic renal scan as the first imaging in the evaluation of mild antenatal hydronephrosis, because there is low risk of underlying anatomic abnormality such as UPJO in the setting of mild hydronephrosis.

Variant 3: Antenatal diagnosis of hydronephrosis with isolated mild (SFU grade 1 and 2 or APRPD less than 15 mm) hydronephrosis on initial neonatal ultrasound.

G. MRI abdomen and pelvis

There is no relevant literature to support the routine use of MRU in the initial evaluation of mild antenatal hydronephrosis.

Variant 4: Male. Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound, or hydronephrosis associated with parenchymal abnormalities, hydroureter, bladder wall thickening, or posterior urethral dilation.

Variant 4: Male. Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound, or hydronephrosis associated with parenchymal abnormalities, hydroureter, bladder wall thickening, or posterior urethral dilation.

A. US Kidneys and Bladder Follow-Up in 1-6 Months

The two most common diagnostic considerations in this situation are VUR and UPJO. Less commonly, PUV or primary megaureter can occur with PUV being the most common cause of neonatal bladder outlet obstruction. PUV occurs in 0.2% to 1% of cases of mild antenatal hydronephrosis but is more frequent (up to 6%) in the setting of more severe antenatal hydronephrosis [51]. With a high index of suspicion for PUV, such as bladder wall-thickening and dilated posterior urethra on US imaging, the bladder should be catheterized at birth to decompress the urinary tract. Beginning prophylactic antibiotics should also be considered [34,50,52]. With more severe postnatal hydronephrosis detected, the need for further workup heightens. Even in the setting of abnormal findings on initial neonatal US, further follow-up US between 1 and 6 months may be useful to re-evaluate a dilated urinary tract after bladder catheterization [1,21,23,53-55].

Variant 4: Male. Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound, or hydronephrosis associated with parenchymal abnormalities, hydroureter, bladder wall thickening, or posterior urethral dilation.

B. Fluoroscopic Voiding Cystourethrography

The purpose of VCUG is to identify the presence of VUR. VUR accounts for 30% of urinary tract abnormalities in infants with antenatal hydronephrosis [31]. In a meta-analysis by Lee et al [51] of over 1,300 subjects, the overall incidence of urinary tract pathology increased with increasing antenatal hydronephrosis, but the risk of VUR was similar for all subjects. Some authors have

shown that with higher grades of postnatal hydronephrosis, the severity of VUR increases [56]. In one study, 121 children were evaluated, and all who had severe VUR had a renal pelvis diameter of ≥10 mm [56]. In a recent multidisciplinary consensus statement on urinary tract dilation, recommendations are for a 1-month US examination and VCUG, in the moderate or severe neonatal hydronephrosis [3].

VUR can be either primary or secondary to other urologic abnormalities. In male patients with moderate or severe hydronephrosis found on neonatal US, VCUG has a role in the evaluation of urologic abnormalities that may need immediate care, and bladder outlet obstruction from PUV must be excluded [12,20,28,29,50,57]. The catheter placed for initial bladder decompression can be used for this study. There is no need to remove the bladder catheter to assess for PUV [58]. Frequently, the study will show VUR in addition to bladder wall thickening and the dilated posterior urethra. When the diagnosis of PUV is made, immediate referral to urology is needed. Furthermore, it can reveal other anomalies such as a duplex collecting system, which helps to determine whether the reflux is primary or secondary.

Other infants with severe or bilateral moderate antenatal hydronephrosis may have VUR in isolation. There is higher risk for UTI in children with VUR [59]. Although the benefit of prophylactic antibiotics in this population is unknown, some authors recommend beginning antibiotics on these patients [26,60].

Variant 4: Male. Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound, or hydronephrosis associated with parenchymal abnormalities, hydroureter, bladder wall thickening, or posterior urethral dilation.

C. Voiding Urosonography

Multiple recent investigations evaluating real-time contrast-enhanced US techniques have demonstrated a high degree of diagnostic accuracy, and some demonstrated increased sensitivity compared to fluoroscopic VCUG in the detection of VUR [41-45]. However, given the significant disadvantage of voiding urosonography in providing lower anatomical detail of the bladder and urethra, it should not be used as the first study for male patients.

Variant 4: Male. Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound, or hydronephrosis associated with parenchymal abnormalities, hydroureter, bladder wall thickening, or posterior urethral dilation.

D. Nuclear Medicine Cystography

Although some studies have suggested equal sensitivity for Tc-99m pertechnetate radionuclide cystography and VCUG [46], it does not provide sufficient anatomical detail of the bladder and urethra and therefore should not be used as the first study for male patients.

Variant 4: Male. Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound, or hydronephrosis associated with parenchymal abnormalities, hydroureter, bladder wall thickening, or posterior urethral dilation.

E. DTPA Renal Scan

Tc-99m DTPA is excreted primarily by glomerular filtration. Its extraction fraction is approximately 20% accounting for greater background, versus renal, activity compared to MAG3 [61]. Tc-99m

DTPA renal scan provides information on renal function and urinary tract drainage based on split renal function and renal washout curves and can be useful for the evaluation of severe grade 3 and 4 hydronephrosis in concert with VCUG [20,29,53,62,63]. Given the lower glomerular filtration rate in newborns, these examinations are frequently delayed until at least 2 months of age [29,63-65]. However, because of its rapid renal clearance and primary excretion by the tubules on which furosemide acts, Tc-99m MAG3 is preferred over Tc-99m DTPA in patients with suspected obstruction or impaired renal function [61].

Variant 4: Male. Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound, or hydronephrosis associated with parenchymal abnormalities, hydroureter, bladder wall thickening, or posterior urethral dilation.

F. MAG3 Renal Scan

Tc-99m MAG3 is primarily excreted through active renal tubular transport, and its extraction fraction is 40% to 50% [61]. This greater extraction fraction, versus DTPA, accounts for less background, versus renal, activity compared to DTPA. Because of its rapid renal clearance and primary excretion by the tubules on which furosemide acts, Tc-99m MAG3 is preferred over Tc-99m DTPA in patients with suspected obstruction or impaired renal function [61]. Tc-99m MAG3 renal scan is useful for the evaluation of severe grade 3 and 4 hydronephrosis and may be performed in concert with a VCUG study [20,29,53,62,63]. Tc-99m MAG3 renal scan provides information on renal function and urinary tract drainage based on split renal function [61].

Diuretic renal scan is used for diagnosis of multiple causes of obstruction, including primary obstructing megaureter [52,66-68]. Approximately 5% to 10% of antenatal hydronephrosis is attributable to primary megaureter [4,69] diagnosed by persistent ureteral dilation (>7 mm). Primary megaureter is classified according to the presence or absence of reflux and obstruction. Most will resolve spontaneously [20,70-72]. Surgical intervention is decided based on evidence of obstruction and depends upon $T_{1/2}$ of time activity curve ($T_{1/2}$ >20 minutes), decreased renal function (<40% differential renal function), deteriorating function (>5% change on consecutive renal scans), or worsening drainage on serial imaging. Tc-99m MAG3 renal scan can be used to monitor function over time, with a decrease in differential renal function on the affected side often serving as an indicator of a need for intervention [55,73].

Variant 4: Male. Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound, or hydronephrosis associated with parenchymal abnormalities, hydroureter, bladder wall thickening, or posterior urethral dilation.

G. MRI Abdomen and Pelvis

There is no consensus on the role of MRU, performed without and with intravenous (IV) contrast, in patients with moderate to severe postnatal hydronephrosis especially before VCUG is performed. Although MRU is not routinely recommended in the initial workup of antenatal hydronephrosis, some authors have argued that it can add value through improved anatomical imaging, for example, in the evaluation of hydronephrosis in the setting of atypical urinary tract anatomy, such as certain duplicated collecting systems or renal dysgenesis [74]. MRU can also adequately assess degree of obstruction [75]. One potential limitation of MRU is that there are systematic differences in estimation of split renal function compared with the gold standard MAG-3 renal scan in kidneys with severely diminished renal function [75] and kidneys with severe hydronephrosis [76].

Variant 5: Female. Antenatal diagnosis of hydronephrosis with moderate or severe (SFU

grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound, or hydronephrosis associated with parenchymal abnormalities, hydroureter, bladder wall thickening.

Variant 5: Female. Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound, or hydronephrosis associated with parenchymal abnormalities, hydroureter, bladder wall thickening.

A. US Kidneys and Bladder Follow-Up in 1–6 Months

The two most common diagnostic considerations in this situation are VUR and UPJO. Less commonly, primary megaureter can occur. Beginning prophylactic antibiotics may be considered [34,50,52]. With more severe postnatal hydronephrosis detected, the need for further workup heightens. Even in the setting of abnormal findings on initial neonatal US, further follow-up US between 1 and 6 months may be useful to re-evaluate a dilated urinary tract after bladder catheterization [1,21,23,53-55].

Variant 5: Female. Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound, or hydronephrosis associated with parenchymal abnormalities, hydroureter, bladder wall thickening.

B. Fluoroscopic Voiding Cystourethrography

The purpose of VCUG is to identify the presence of VUR. VUR accounts for 30% of urinary tract abnormalities in infants with antenatal hydronephrosis [31]. In a meta-analysis by Lee et al [51] of over 1,300 subjects, the overall incidence of urinary tract pathology increased with increasing antenatal hydronephrosis, but the risk of VUR was similar for all subjects. Some authors have shown that with higher grades of postnatal hydronephrosis, the severity of VUR increases [56]. In one study, 121 children were evaluated, and all who had severe VUR had a renal pelvis diameter of ≥10 mm [56]. In a recent multidisciplinary consensus statement on urinary tract dilation, recommendations are for a 1-month US examination and VCUG, in the moderate or severe neonatal hydronephrosis [3].

VUR can be either primary or secondary to other urologic abnormalities. In patients with moderate or severe hydronephrosis found on neonatal US, VCUG has a role in the evaluation of urologic abnormalities that may need immediate care [12,20,28,29,50,57]. Furthermore, it can reveal other anomalies, such as a duplex collecting system, which help to determine whether the reflux is primary or secondary.

Other infants with severe or bilateral moderate antenatal hydronephrosis may have VUR in isolation. There is higher risk for UTI in children with VUR [59]. Although the benefit of prophylactic antibiotics in this population is unknown, some authors recommend beginning antibiotics on these patients [26,60].

Variant 5: Female. Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound, or hydronephrosis associated with parenchymal abnormalities, hydroureter, bladder wall thickening.

C. Voiding Urosonography

Multiple recent investigations evaluating real-time contrast-enhanced US techniques have

demonstrated a high degree of diagnostic accuracy, and some demonstrated increased sensitivity as compared to fluoroscopic VCUG in the detection of VUR [41-45]. The main potential disadvantage of voiding urosonography is a lower anatomical detail of the bladder, but otherwise, arguments for and against using voiding urosonography are similar to that of VCUG.

Variant 5: Female. Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound, or hydronephrosis associated with parenchymal abnormalities, hydroureter, bladder wall thickening.

D. Nuclear Medicine Cystography

Some studies have suggested equal sensitivity for Tc-99m pertechnetate radionuclide cystography and VCUG [46], whereas others have indicated that radionuclide cystography has improved sensitivity for VUR in infants up to 1 year of age [47]. Arguments for and against using radionuclide cystography are similar to that of VCUG for the female patient.

Variant 5: Female. Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound, or hydronephrosis associated with parenchymal abnormalities, hydroureter, bladder wall thickening.

E. DTPA Renal Scan

Tc-99m DTPA is excreted primarily by glomerular filtration. Its extraction fraction is approximately 20% accounting for greater background, versus renal, activity compared to MAG3 [61]. Tc-99m DTPA renal scan provides information on renal function and urinary tract drainage based on split renal function and renal washout curves and can be useful for the evaluation of severe grade 3 and 4 hydronephrosis in concert with VCUG [20,29,53,62,63]. Given the lower glomerular filtration rate in newborns, these examinations are frequently delayed until at least 2 months of age [29,63-65]. However, because of its rapid renal clearance and primary excretion by the tubules on which furosemide acts, Tc-99m MAG3 is preferred over Tc-99m DTPA in patients with suspected obstruction or impaired renal function [61].

Variant 5: Female. Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound, or hydronephrosis associated with parenchymal abnormalities, hydroureter, bladder wall thickening.

F. MAG3 Renal Scan

Tc-99m MAG3 is primarily excreted through active renal tubular transport, and its extraction fraction is 40% to 50% [61]. This greater extraction fraction, versus DTPA, accounts for less background, versus renal, activity compared to DTPA. Because of its rapid renal clearance and primary excretion by the tubules on which furosemide acts, Tc-99m MAG3 is preferred over Tc-99m DTPA in patients with suspected obstruction or impaired renal function [61]. Tc-99m MAG3 renal scan is useful for the evaluation of severe grade 3 and 4 hydronephrosis and may be performed in concert with a VCUG study [20,29,53,62,63]. Tc-99m MAG3 renal scan provides information on renal function and urinary tract drainage based on split renal function [61].

Diuretic renal scan is used for diagnosis of multiple causes of obstruction, including primary obstructing megaureter [52,66-68]. Approximately 5% to 10% of antenatal hydronephrosis is attributable to primary megaureter [4,69] diagnosed by persistent ureteral dilation (>7 mm). Primary megaureter is classified according to the presence or absence of reflux and obstruction.

Most will resolve spontaneously [20,70-72].

Surgical intervention is decided based on evidence of obstruction and depends upon $T_{1/2}$ of time activity curve ($T_{1/2} > 20$ minutes), decreased renal function (<40% differential renal function), deteriorating function (>5% change on consecutive renal scans), or worsening drainage on serial imaging. Tc-99m MAG3 renal scan can be used to monitor function over time, with a decrease in differential renal function on the affected side often serving as an indicator of a need for intervention [55,73].

Variant 5: Female. Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound, or hydronephrosis associated with parenchymal abnormalities, hydroureter, bladder wall thickening.

G. MRI Abdomen and Pelvis

There is no consensus on the role of MRU, performed without and with IV contrast, in patients with moderate to severe postnatal hydronephrosis especially before VCUG is performed. Although MRU is not routinely recommended in the initial workup of antenatal hydronephrosis, some authors have argued that it can add value through improved anatomical imaging, for example, in the evaluation of hydronephrosis in the setting of atypical urinary tract anatomy, such as certain duplicated collecting systems or renal dysgenesis [74]. MRU can also adequately assess degree of obstruction [75]. One potential limitation of MRU is inaccurate estimation of split renal function compared with renal scan in kidneys with severely diminished renal function [75] and kidneys with severe hydronephrosis [76].

Variant 6: Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound and no evidence of reflux on VCUG.

Variant 6: Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound and no evidence of reflux on VCUG.

A. US Kidneys and Bladder Follow-Up in 1-6 Months

When moderate or severe antenatal hydronephrosis is present on initial neonatal US, and VUR is not present, obstructive causes of hydronephrosis must be excluded. In the absence of hydroureter or high grade VUR, UPJO should be considered [6,29,53,77]. Of the causes of hydronephrosis, UPJO accounts for approximately 10% to 65% of cases and in 90% of cases the obstruction is unilateral [2,4,22,48]. As the severity of hydronephrosis increases, the risk of UPJO also increases, and as much as 35% of significant hydronephrosis (>10 mm APRPD postnatally) was attributable to UPJO in one study. Lee et al [51] showed a 54% risk of UPJO in severe (>15 mm APRPD postnatally) urinary tract dilation. Even in the setting of abnormal findings on initial neonatal US, further follow-up US between 1 and 6 months may be useful to re-evaluate a dilated urinary tract after bladder catheterization [1,21,23,53-55].

Variant 6: Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound and no evidence of reflux on VCUG.

B. DTPA Renal Scan

Tc-99m DTPA is excreted primarily by glomerular filtration. Its extraction fraction is approximately 20% accounting for greater background, versus renal, activity compared to MAG3 [61]. Tc-99m

DTPA renal scan provides information on renal function and urinary tract drainage based on split renal function and renal washout curves and can be useful for the evaluation of severe grade 3 and 4 hydronephrosis [20,29,53,62,63]. Given the lower glomerular filtration rate in newborns, these examinations are frequently delayed until at least 2 months of age [29,63-65]. However, because of its rapid renal clearance and primary excretion by the tubules on which furosemide acts, Tc-99m MAG3 is preferred over Tc-99m DTPA in patients with suspected obstruction or impaired renal function [61].

Variant 6: Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound and no evidence of reflux on VCUG.

C. MAG3 Renal Scan

Tc-99m MAG3 is primarily excreted through active renal tubular transport, and its extraction fraction is 40% to 50%. This greater extraction fraction, versus DTPA, accounts for less background, versus renal, activity compared to DTPA. Because of its rapid renal clearance and primary excretion by the tubules on which furosemide acts, Tc-99m MAG3 is preferred over Tc-99m DTPA in patient with suspected obstruction or impaired renal function [61]. Tc-99m MAG3 renal scan provides information on split renal function and urinary tract drainage based on renal washout curve [3,22,27,28].

Diuretic renal scan is used for diagnosis of multiple causes of obstruction, including primary obstructing megaureter [52,66-68]. Approximately 5% to 10% of antenatal hydronephrosis is attributable to primary megaureter [4,69] diagnosed by persistent ureteral dilation (>7 mm). Primary megaureter is classified according to the presence or absence of reflux and obstruction. Most will resolve spontaneously [20,70-72].

Surgical intervention is decided based on evidence of obstruction based on $T_{1/2}$ of time activity curve ($T_{1/2} > 20$ minutes), decreased renal function (<40% differential renal function), deteriorating function (>5% change on consecutive renal scans), or worsening drainage on serial imaging [55,73]. Tc-99m MAG3 renal scan can be used to monitor function over time, with a decrease in differential renal function on the affected side often serving as an indicator of a need for intervention [55,73].

Variant 6: Antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis on initial neonatal ultrasound and no evidence of reflux on VCUG.

D. MRI Abdomen and Pelvis

There is no consensus on the role of MRU, performed without and with IV contrast, in patients with moderate to severe postnatal hydronephrosis. Although MRU is not routinely recommended in the initial workup of antenatal hydronephrosis, some authors have argued that it can add value through improved anatomical imaging, for example, in the evaluation of hydronephrosis in the setting of atypical urinary tract anatomy, such as certain duplicated collecting systems or renal dysgenesis [74]. MRU can also adequately assess degree of obstruction [75]. One potential limitation of MRU is that there are systematic differences in estimation of split renal function compared with renal scan in kidneys with severely diminished renal function and kidneys with severe hydronephrosis [76].

Summary of Highlights

- **Variant 1**: US kidneys and bladder retroperitoneal is usually appropriate for the initial imaging of neonates with an antenatal diagnosis of hydronephrosis.
- **Variant 2**: A follow-up in 1 to 6 months with an US kidneys and bladder retroperitoneal is usually appropriate for neonates with a normal US and an antenatal diagnosis of hydronephrosis.
- **Variant 3**: A follow-up in 1 to 6 months with an US kidneys and bladder retroperitoneal is usually appropriate for neonates with an antenatal diagnosis of hydronephrosis and isolated mild (SFU grade 1 and 2) hydronephrosis on initial US.
- **Variant 4**: US kidneys and bladder retroperitoneal follow-up in 1 to 6 months, fluoroscopy VCUG, or MAG3 renal scan is usually appropriate for a male child with an antenatal diagnosis of hydronephrosis and moderate or severe (SFU grade 3 or 4 or APRPD > 15 mm) hydronephrosis on initial neonatal US, or hydronephrosis associated with parenchymal abnormalities, hydroureter, bladder wall thickening, or posterior urethral dilation. These procedures are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient's care).
- Variant 5: US kidneys and bladder retroperitoneal follow-up in 1 to 6 months, fluoroscopy VCUG, voiding urosonography, or MAG3 renal scan is usually appropriate for a female child with an antenatal diagnosis of hydronephrosis and moderate or severe (SFU grade 3 or 4 or APRPD >15 mm) hydronephrosis on initial neonatal US, or hydronephrosis associated with parenchymal abnormalities, hydroureter, or bladder wall thickening. These procedures are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient's care).
- **Variant 6**: US kidneys and bladder retroperitoneal follow-up in 1 to 6 months or MAG3 renal scan is usually appropriate for a child with no evidence of reflux on VCUG on initial US and an antenatal diagnosis of hydronephrosis with moderate or severe (SFU grade 3 or 4 or APRPD greater than 15 mm) hydronephrosis. These procedures are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient's care).

Supporting Documents

The evidence table, literature search, and appendix for this topic are available at https://acsearch.acr.org/list. The appendix includes the strength of evidence assessment and the final rating round tabulations for each recommendation.

For additional information on the Appropriateness Criteria methodology and other supporting documents, please go to the ACR website at https://www.acr.org/Clinical-Resources/Clinical-Tools-and-Reference/Appropriateness-Criteria.

Appropriateness Category Names and Definitions

| Appropriateness Category Name | Appropriateness Rating | Appropriateness Category Definition |
|-------------------------------|---------------------------|--|
| Usually Appropriate | 7, 8, or 9 | The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable riskbenefit ratio for patients. |
| May Be Appropriate | 4, 5, or 6 | The imaging procedure or treatment may be |

| | | indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal. |
|--------------------------------------|------------|--|
| May Be Appropriate (Disagreement) | 5 | The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel's recommendation. "May be appropriate" is the rating category and a rating of 5 is assigned. |
| Usually Not Appropriate | 1, 2, or 3 | The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable. |

Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, because of both organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared with those specified for adults (see Table below). Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria Radiation Dose Assessment Introduction document.

Relative Radiation Level Designations

| Relative Radiation Level* | Adult Effective Dose Estimate Range | Pediatric Effective Dose Estimate Range |
|---------------------------|--|--|
| 0 | 0 mSv | 0 mSv |
| * | <0.1 mSv | <0.03 mSv |
| ★ | 0.1-1 mSv | 0.03-0.3 mSv |
| | 1-10 mSv | 0.3-3 mSv |
| | 10-30 mSv | 3-10 mSv |
| | 30-100 mSv | 10-30 mSv |

^{*}RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."

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Disclaimer

The ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

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